UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

IN RE VANDA PHARMACEUTICALS INC. DERIVATIVE LITIGATION	Case No. 1:19-cv-04293-FB-LB **JURY TRIAL DEMANDED**

CONSOLIDATED VERIFIED STOCKHOLDER DERIVATIVE COMPLAINT

Plaintiffs Samuel Williams and Michael Bavaro ("Plaintiffs"), by and through their undersigned attorneys, bring this action derivatively on behalf of Vanda Pharmaceuticals Inc. ("Vanda" or the "Company") and allege the following upon information and belief, except as to those allegations pertaining to themselves, which are made upon personal knowledge. Plaintiffs' information and belief is based upon, among other things, their counsel's investigation, which includes, without limitation: (a) review and analysis of public filings in *United States of America, et al., ex rel. Richard Gardner v. Vanda Pharmaceuticals Inc.*, Case No. 1:17-cv-00464 (APM) (D.D.C.) (the "Qui Tam Lawsuit"); (b) review and analysis of public filings in *Gordon v. Vanda Pharmaceuticals Inc., et al.*, Case No. 1:19-cv-01108-FB-LB (E.D.N.Y.) (the "Securities Class Action"); (c) review and analysis of public filings in *Vanda Pharmaceuticals, Inc., et al., v. Food and Drug Administration*, et al., Case No. 19-cv-301 (JDB) (D.D.C.) (the "FDA Litigation"); (d) review and analysis of regulatory filings made by Vanda with the United States Securities and Exchange Commission (the "SEC"); (e) review and analysis of press releases and media reports issued and disseminated by Vanda; and (f) review of other publicly available information concerning Vanda.

INTRODUCTION

1. This is a stockholder derivative action brought on behalf of Vanda against certain of its officers and directors seeking to remedy breaches of their fiduciary duty, violations of the federal securities laws, and unjust enrichment, which caused and continue to cause substantial harm to the Company. This misconduct began on November 4, 2015 and continued through February 11, 2019 (the "Relevant Period"). This misconduct damaged Vanda's reputation, goodwill, and community standing and exposed the Company to millions of dollars in potential liability for violations of state and federal laws.

2. Vanda is a biopharmaceutical company that focuses on the development and commercialization of products for the treatment of central nervous system disorders. Vanda owns and markets two drugs: (i) Fanapt® (iloperidone) ("Fanapt"), a drug for the treatment of schizophrenia, and (ii) HETLIOZ® (tasimelteon) ("Hetlioz"), a drug for the treatment of non-24-hour sleep-wake disorder ("Non-24").[1] Vanda derived all of its revenue from sales of Fanapt and Hetlioz during the Relevant Period.

3. Since at least November 2015, the Company schemed to promote its drugs Fanapt and Hetlioz for "off-label" uses[2] in addition to employing several other prohibited promotional strategies.

[1] Non-24 is a circadian rhythm sleep disorder in which a person's biological clock fails to synchronize to a 24-hour day. Instead of sleeping roughly the same time every day, a person with Non-24 would find their sleep time gradually delayed by minutes to hours every day.

[2] "Off-label" use is use of a medication for an indication, in an age group, with a dosage, or through a route of administration that has not been approved by The Food and Drug Administration ("FDA").

4. For Fanapt, Vanda trained its sales representatives to promote the drug off-label in a variety of ways, including: (i) marketing Fanapt to treat mental disorders other than schizophrenia; (ii) focusing on akathisia,[3] a side effect of antipsychotics, in an effort to generate sales to non-schizophrenia patients; (iii) providing unrealistic sales targets that required off-label promotion in order to be met; (iv) compensating sales representatives for off-label sales; (v) marketing efforts targeting pediatric patients even though Fanapt is only FDA-approved for use by adults; (vi) presenting Fanapt as a first line treatment even though it is only FDA-approved as a second line treatment;[4] (vii) downplaying the extent and severity of QT prolongation, a serious and sometimes fatal side effect of Fanapt;[5] and (viii) promoting that Fanapt can be taken once daily even though it is only FDA-approved to be taken twice daily.

5. As to Hetlioz, although Vanda repeatedly acknowledged that the Non-24 drug was intended only for use in blind people, Defendants (defined below) realized that the number of blind people with Non-24 was very small and therefore caused the Company to target psychiatrists treating sighted people. Defendants focused their sales efforts for Hetlioz on sighted people who were having trouble sleeping – not those who received a diagnosis for Non-24, which is exceedingly rare in sighted people. These efforts caused Hetlioz, which cost $180,000 for an annual supply during the Relevant Period, to be marketed off-label during the Relevant Period.

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[3] Akathisia is an uncontrollable feeling of restlessness and urge to move, manifesting in behaviors such as rocking back and forth, walking in place, or crossing and uncrossing legs while sitting.

[4] Second line treatments should not be used unless the patient has tried another antipsychotic first.

[5] QT prolongation is an arrhythmia where the heart takes longer than normal to recharge between beats.

6. Federal health care programs, including Medicare, Medicaid, and Tricare, reimbursed these improper off-label prescriptions in violation of the federal False Claim Act, 31 U.S.C. § 3729 (the "FCA"), state false claims acts, the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (the "FD&C Act"), and applicable regulatory and ethical guidance.

7. As a result of Defendants' misconduct, Vanda is facing significant liability from the Qui Tam Lawsuit filed by a relator on behalf of the United States of America; the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, and Washington; the Commonwealths of Massachusetts and Virginia; the District of Columbia; and the policyholders of various insurance companies. Vanda has incurred substantial expenses relating to the investigation of the abovementioned misconduct, including legal fees and expenses and the potential for liability to the United States, the individual States, and insurance companies, and regulatory fines and penalties.

8. The Qui Tam Lawsuit alleges that the Company's executives and officers, including Vanda's President and Chief Executive Officer, Mihael H. Polymeropoulos ("Polymeropoulos"), and Senior Vice President, Gian Piero Reverberi ("Reverberi"), knew about, condoned, and actively participated in the fraudulent scheme to promote both Hetlioz and Fanapt off-label. By consciously and reckless disregarding their fiduciary duty of care and loyalty, the Defendants have brought consequential harm to Vanda.

9. This misconduct also has resulted in the Company being named a defendant in the Securities Class Action, which alleges that the Company failed to disclose to investors that: (i) Vanda was engaged in a fraudulent scheme to promote the off-label use of Fanapt and Hetlioz;

(ii) Vanda defrauded the government by violating Medicare, Medicaid, and Tricare programs; (iii) as a result of the scheme, Vanda faced the Qui Tam Lawsuit; (iv) Vanda's promotional materials for Fanapt and Hetlioz were false and misleading, garnering regulatory scrutiny from the FDA; and (v) as a result, Defendants' statements about Vanda's business, operations and prospects lacked a reasonable basis and were materially false and misleading.

10. The off-label promotion scheme for Fanapt and Hetlioz was further revealed in a short seller report by Aurelius Value issued on February 11, 2019 (the "Aurelius Report").

11. Defendants also made materially false and misleading statements and omissions during the Relevant Period concerning tradipitant, used for the treatment of itchiness from eczema, which was Vanda's most important drug in the clinical trial stage.

12. In May 2018, unbeknownst to the investing public, the FDA warned Vanda that if the Company wanted to study tradipitant in humans for longer than three months, which was required for the drug to receive FDA approval, Vanda would need to first conduct a nine-month non-rodent safety study to ensure that tradipitant was safe for human use.

13. The FDA told Defendants that if Vanda failed to do the required safety study, the FDA would enforce a clinical trial hold on tradipitant. A clinical trial hold is an order rarely issued by the FDA to delay or suspend a drug trial. Such an order would be catastrophic for the Company.

14. Despite being fully aware of the FDA's position by May 2018, Defendants nevertheless continued to conduct tradipitant studies in humans lasting longer than three months. Accordingly, in December 2018, the FDA ordered a clinical trial hold for tradipitant, placing the commercial future of tradipitant in peril.

15. Thus, at all relevant times from May 2018 until the end of the Relevant Period,

Defendants knew, or recklessly disregarded, that Vanda was prohibited from conducting a safety study for tradipitant as required by the FDA. Despite this, Defendants made, and caused Vanda to make, numerous statements to investors regarding the progress of clinical trials for tradipitant, omitting this critical information.

16. On February 5, 2019, the truth regarding tradipitant emerged when the Company commenced the FDA Litigation (defined below).

17. The Company was substantially damaged by Defendants' knowing breaches of fiduciary duty and other violations of law. Plaintiffs bring this action against Defendants to remedy their misconduct.

18. The Company's Board of Directors (the "Board") failed in its duty of care and oversight in the face of these serious violations of federal and state laws and regulations. The Board's sustained failure to ensure effective corporate governance and compliance was the result of Defendants' knowing breach or reckless disregard of their fiduciary duties. The Board was inattentive and consciously turned a blind eye to the fraudulent promotion scheme, abuse of government healthcare programs, and failure to follow FDA regulations.

19. Accordingly, Plaintiffs seek needed reforms to corporate governance, management policy, and procedural changes to ensure that the Company complies with federal and state laws and regulations. Plaintiffs, on behalf of Vanda, also seek monetary damages from the Defendants, who abandoned their fiduciary duties and should be held accountable for the harm suffered by Vanda.

JURISDICTION AND VENUE

20. Pursuant to 28 U.S.C. § 1331 and Section 27 of the Securities Exchange Act of 1934 (the "Exchange Act"), the Court has jurisdiction over the claims asserted herein for

violations of sections 10(b) and 14(a) of the Exchange Act and SEC Rule 14a-9 promulgated thereunder.

21. The Court has supplemental jurisdiction pursuant to 28 U.S.C. § 1367(a) over all other claims that are so related to claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution. This action is not a collusive action designed to confer jurisdiction on a court of the United States that it would not otherwise have.

22. The Court has jurisdiction over each defendant named herein because each defendant is either a corporation that conducts business and maintains operations in this District or is an individual who has sufficient minimum contacts with this District to render the exercise of jurisdiction by the Court permissible under traditional notions of fair play and substantial justice.

23. Venue is proper in this District pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391(b) as the Company conducts business in this District and engages in numerous activities which had an effect in this District. Defendants have also consented to venue in this District.

PARTIES

Plaintiffs

24. Plaintiff Samuel Williams is a current shareholder of Vanda and has continually held Vanda stock at all relevant times.

25. Plaintiff Michael Bavaro is a current shareholder of Vanda and has continually held Vanda stock at all relevant times.

Nominal Defendant

26. Nominal Defendant Vanda is incorporated in Delaware and maintains its headquarters at 2200 Pennsylvania Avenue NW, Washington D.C. 20037. Vanda is a global biopharmaceutical company that focuses on the development and commercialization of products for the treatment of central nervous system disorders. Vanda sells, markets, and promotes its products throughout the United States, including New York. Vanda's common stock is publicly traded on NASDAQ under the symbol "VNDA."

Defendants

27. Defendant Polymeropoulos co-founded Vanda in 2003 and has served as the Company's President, Chief Executive Officer ("CEO"), and a member of the Board since May 2003. Polymeropoulos is a psychiatrist who holds a degree in medicine from the University of Patras. He is named as a defendant in the Securities Class Action. According to Forms DEF14A filed by Vanda with the SEC on April 22, 2020 and April 25, 2019, Defendant Polymeropoulos received at least the following compensation during the Relevant Period:[6]

2019:	$4,278,137
2018:	$4,024,728
2017:	$6,265,989
2016:	$7,185,457
Total:	**$21,754,311**

28. Defendant H. Thomas Watkins ("Watkins") has served as Chairman of the Board since March 2014 and has been a member of the Board since 2006. He serves as the Chairman of the Nominating/Corporate Governance Committee and as a member of the Compensation Committee.

[6] Compensation data for 2016 is from the Form DEF14A dated April 25, 2019 and for 2017, 2018 and 2019 is from the Form DEF14A dated April 22, 2020.

29. Defendant Michael F. Cola ("Cola") was a director of the Company from 2012 until he resigned from the Board effective February 14, 2020. He served on the Audit Committee and Compensation Committee.

30. Defendant Kenneth M. Bate ("Bate") served as a director of the Company from December 2015 until June 2018. Defendant Bate did not stand for re-election at the 2018 Annual Meeting when his term expired on June 13, 2018. He served on the Compensation Committee.

31. Defendant Richard W. Dugan ("Dugan") has been a director of the Company since 2005. He serves as the Chairman of the Audit Committee and as a member of the Nominating/Corporate Governance Committee.

32. Defendant Vincent J. Milano ("Milano") served as a director of the Company from 2010 until his resignation on June 13, 2019 at the 2019 Annual Meeting. He served as the Chairman of the Compensation Committee and as a member of the Audit Committee

33. Defendant Howard H. Pien ("Pien") served as a director of the Company from 2007 until June 2016. He served as Chairman of the Board from December 2010 until March 2014. He did not stand for re-election when his term expired on June 16, 2016 following the 2016 Annual Meeting. He served on the Compensation Committee and was succeeded by Defendant Bate upon the expiration of his term on June 16, 2016.

34. Defendant James P. Kelly ("Kelly") has served as Vanda's Executive Vice President, Chief Financial Officer and Treasurer since February 2017 and as Secretary since April 2018. Previously, he served as Vanda's Senior Vice President, Chief Financial Officer and Treasurer from December 2010 through February 2017 and as Secretary from December 2010 to September 2015. Defendant Kelly is named as a defendant in the Securities Class Action. He received at least the following compensation during the Relevant Period:

2019:	$2,248,410
2018:	$2,401,385
2017:	$2,276,307
2016:	$2,189,029
Total:	**$9,115,131**

35. Defendant Reverberi ("Reverberi") has served as Vanda's Senior Vice President and Chief Commercial Officer ("CCO") since April 2016 and served as Vanda's Senior Vice President, Acting CCO, and European General Manager from December 2015 to April 2016. He was Vanda's Senior Vice President and European General Manager from September 2015 to December 2015. He is named as a defendant in the Securities Class Action. He received the following compensation during the Relevant Period:

2019:	$2,296,319
2018:	$2,145,907
2017:	$1,755,570
2016:	$1,734,494
Total:	**$7,932,290**

36. Defendants identified in paragraphs 26 through 34 are collectively referred to as the "Defendants."

37. Defendants Polymeropoulos, Watkins, Cola, Bate, Dugan, Milano and Pien are collectively referred to as the "Director Defendants."

38. Defendants Polymeropoulos, Kelly, and Reverberi are collectively referred to as the "Officer Defendants."

Non-Parties

39. Non-Party Thomas Gibbs ("Gibbs") served as the Company's Senior Vice President and CCO from April 2015 until his departure in December 2015. Gibbs did not work at Vanda before April 2015. Gibbs, who is currently the CCO of Optinose, Inc., another pharmaceutical company, has spent his career working in the biotechnology and pharmaceutical industries. On December 21, 2015, Vanda filed a Form 8-K (the "12/21/15 Form 8-K")

disclosing, among other things, that Gibbs had resigned from the Company after only eight months and that "he is not entitled to any severance or other post-termination benefits."

THE FIDUCIARY DUTIES OF VANDA'S OFFICERS AND DIRECTORS

40. Each officer and director of Vanda owed the Company the duty to exercise a high degree of care, loyalty, and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct complained of herein involves fraudulent misconduct by Vanda's directors and officers – a knowing, intentional, and culpable violation of their obligations as directors and/or officers of Vanda, and the absence of good faith on their part concerning their duties to the Company. The officers' misconduct was ratified by the Board, which failed to take any legal action on behalf of the Company against them.

41. By reason of their positions as officers and/or directors of Vanda and because of their ability to control the business and corporate affairs of Vanda, Defendants owe Vanda fiduciary duties of good faith, loyalty, and candor. The Defendants were and are required to use their utmost ability to control and manage Vanda in a fair, just, honest, and equitable manner. The Defendants were, and are, required to act in furtherance of the best interests of Vanda and not in furtherance of their own personal interest or benefit. Each director and officer of the Company owes Vanda the highest obligations of fair dealing and the fiduciary duty to exercise good faith and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets.

42. To fulfill their responsibilities and duties, the directors and officers of Vanda must supervise and manage Vanda's policies, controls in compliance with applicable controlling

statutes. Vanda's directors are each made aware of their duties and responsibilities when, upon joining the Board, they undergo mandatory training and education on fiduciary obligations.

43. In addition to these fiduciary duties, the directors' and officers' oversight and management obligations require them to know of and oversee compliance with the laws and regulations that apply to Vanda's business. As a pharmaceutical company, Vanda is subject to extensive regulation and regulatory oversight from both the federal government and each of the States that it operates within.

44. The FD&C Act empowers the FDA to regulate the manufacture, sale, and distribution of drugs and devices in the United States. This authority includes oversight of promotional labeling and advertising for prescription drugs. 21 U.S.C. § 502. Vanda is required to cooperate with the FDA and operate in accordance with the statutory requirements of the FD&C Act.

45. The Defendants, because of their positions of control and authority as directors and/or officers of Vanda, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein. Because of their supervisory, executive, managerial, and directorial positions with Vanda, each Defendant had knowledge of material non-public information about the financial condition, operations, and future business prospects of Vanda.

46. To discharge their duties, the Defendants (the officers and directors of Vanda) were required to exercise reasonable and prudent supervision over the management, policies, practices and controls of the Company. By virtue of such duties, the Defendants were required to, among other things:

a) Exercise good faith to ensure that the affairs of the Company were conducted in an efficient, business-like manner to make it possible to provide the highest quality performance of their business;

b) Exercise good faith to ensure that the Company operated in a diligent, honest, and prudent manner and complied with all applicable federal and state laws, rules, regulations, and requirements as well as all contractual obligations, including acting only within the scope of its legal authority and disseminating only truthful and accurate statements to the investing public;

c) Properly and accurately guide investors and analysts as to the true financial condition of the Company at any given time, including making accurate statements about the Company's financial results;

d) When put on notice of problems with the Company's business practices and operations, exercise good faith in taking appropriate action to correct the problems and prevent their recurrence; and

e) Exercise their authority to claw back compensation from the directors and officers responsible for the above improprieties.

47. Each Defendant, as an executive officer or director, owed to the Company and to its shareholders the fiduciary duties of loyalty and due care in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of the Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of the Company, the absence of good faith on their part, and a reckless disregard for their duties to the Company and its shareholders, which the Defendants were aware or should have been aware posed a risk of serious injury to the Company.

48. As directors and officers, the Defendants are subject to the Company's Code of Business Conduct and Ethics (the "Code of Conduct"),[7] the purpose of which is to "deter wrongdoing and to promote:"

> (a) Honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;
>
> (b) Full, fair, accurate, timely and understandable disclosure in reports and documents that the Company files with, or submits to, the Securities and Exchange Commission (the "SEC") and in other public communications made by the Company;
>
> (c) Compliance with applicable governmental laws, rules and regulations including, without limitation, the rules and regulations of the SEC, the federal Occupational Safety and Health Act, the U.S. Foreign Corrupt Practices Act (the "FCPA"), the Federal Food, Drug, and Cosmetic Act and the rules and regulations of the U.S. Food and Drug Administration (the "FDA"), the anti-kickback provisions of the federal Social Security Act and Department of Health and Human Services Office of the Inspector General regulations, the federal False Claims Act, and comparable state laws.

49. The Code of Conduct also provides in relevant part as follows:[8]

> 4. **COMPLIANCE WITH APPLICABLE LAWS, RULES AND REGULATIONS**
>
> Obeying the law, both in letter and spirit, is the foundation on which the Company's ethical standards are built. **You must comply with all applicable laws, rules and regulations of the cities, states, provinces and countries in which we operate.** Although you are not expected to know the details of these laws, it is important to know enough to determine when to seek advice from managers or other appropriate personnel. If a law conflicts with a policy in the Code, you must comply with the law. If you have any questions about these conflicts, ask your manager or the Company's Compliance Officer how to handle the situation.

[7] Available at https://vandapharmaceuticalsinc.gcs-web.com/static-files/3bc193a2-45a7-4b99-870c-eb30c53ff6be (last visited April 20, 2020).

[8] Emphasis is added to all quotations throughout this Complaint unless otherwise noted.

5. **ETHICAL CONDUCT**

Beyond compliance with laws, the Company requires that all its employees, officers, and directors act in a manner that meets the highest standards of ethical behavior.

* * *

7. **PUBLIC DISCLOSURE OF INFORMATION**

(a) The federal securities laws require the Company to disclose certain information in various reports that the Company must file with or submit to the SEC. In addition, from time to time, the Company makes other public communications, such as issuing press releases.

(b) The Company expects all directors, officers and employees who are involved in the preparation of SEC reports or other public documents to ensure that the information disclosed in those documents is full, fair, accurate, timely and understandable.

(c) To the extent that you reasonably believe that questionable accounting or auditing conduct or practices have occurred or are occurring, report those concerns to the Company's Chief Executive Officer, Chief Financial Officer or Compliance Officer or in accordance with the Company's Whistleblower policy.

* * *

12. **RECORD-KEEPING**

(a) The Company requires honest and accurate recording and reporting of information in order to make responsible business decisions and to comply with the law. For example, employees who must report their hours worked must only report the true and actual number of hours worked (whether for purposes of individual pay or for purposes of reporting such information to customers). The Company also requires each director and employee to disclose any transaction or arrangement among such individual or any family member or affiliated entity of such individual, on the one hand, and any other director, employee or any family member or affiliated entity of such other individual, on the other hand, that in any way relates to or arises out of such individual's professional relationship with the Company.

(b) Many employees regularly use business expense accounts, which must be documented and recorded accurately in accordance with the

Company's policies. If you are not sure whether you may seek reimbursement for a certain expense, ask your manager or the Compliance Officer.

(c) All of the Company's books, records, accounts and financial statements must be maintained in reasonable detail, must appropriately reflect the Company's transactions and must conform both to applicable legal requirements and to the Company's system of internal controls. Unrecorded or "off the books" funds or assets should not be maintained unless permitted by applicable law or regulation.

(d) Business records and communications often become public, and you should avoid exaggeration, derogatory remarks, guesswork or inappropriate characterizations of people and companies that can be misunderstood. This policy applies equally to e-mail, internal memos and formal reports. Records should always be retained or destroyed according to the Company's record retention policies. In accordance with those policies, in the event of litigation or governmental investigation, please consult the Company's Compliance.

* * *

15. **COMPETITION AND FAIR DEALING**

The Company seeks to outperform its competition fairly and honestly. Using or disclosing, or encouraging others to use or disclose, other companies' proprietary, confidential or trade secret information, without the owner's prior consent, and any theft or misappropriation of such information is strictly prohibited. You should endeavor to respect the rights of and deal fairly with the Company' customers, suppliers, competitors and employees.

* * *

18. **SPECIAL ETHICS OBLIGATIONS FOR EMPLOYEES WITH FINANCIAL REPORTING RESPONSIBILITIES**

(a) As a public company, it is important that the Company's filings with the SEC be accurate and timely. Depending on your position within the Company, you may be called upon to provide information to assure that the Company's public reports are complete, fair and understandable. The Company expects you to take this responsibility seriously and to provide prompt and accurate answers to inquiries related to the Company's public disclosure requirements.

(b) The Finance department bears a special responsibility for promoting integrity throughout the organization, with responsibilities to stakeholders both inside and outside the Company. The Chief Executive Officer, Chief Financial Officer, Controller and other finance personnel each have a special role both to adhere to these principles themselves and also to ensure that a culture exists throughout the Company as a whole that ensures that fair and timely reporting of financial results and conditions.

(c) Because of this special role, the Chief Executive Officer, Chief Financial Officer or Controller and all other and all members of the Company's finance department are bound by the following Financial Officer Code of Ethics. Each agrees that he or she will:

(i) Act with honesty and integrity;

(ii) Avoid actual or apparent conflicts of interest in professional and personal relationships;

(iii) Provide information that is accurate, complete, objective, relevant, timely and understandable to ensure full, fair, accurate timely and understandable disclosure in reports and documents that the Company files with, or submits to, government agencies and in other public communications;

(iv) Accept responsibility for the full, fair, accurate, timely and understandable disclosure in the periodic reports required to be filed by the Company with the SEC;

(v) Bring promptly to the attention of the Chief Executive Officers, Chief Financial Officer or Compliance Officer any material information of which he or she may become aware that affects the disclosures made by the Company in its public filings;

(vi) Bring to the attention of the Chief Executive Officer, Chief Financial Officer, Compliance Officer or Audit Committee of the Company any significant deficiencies in the design or operation of internal controls which could adversely affect the Company's ability to record, process, summarize and report financial data;

(vii) Bring to the attention of the Chief Executive Officer, Chief Financial Officer, Compliance Officer or Audit Committee of the Company any fraud that involves management or other employees who have a significant role in the Company's financial reporting, disclosures or internal controls;

(viii) Bring to the attention of the Chief Executive Officer, Chief Financial Officer, Compliance Officer or Audit Committee any information concerning any violation of this Code, including any conflicts of interest involving any employees who have a significant role in the Company's financial reporting, disclosures or internal controls; and

(ix) Bring to the attention of the Chief Executive Officer, Chief Financial Officer, Compliance Officer or Audit Committee any information concerning a material violation of the securities or other laws, rules or regulations applicable to the Company and the operation of its business.

* * *

19. **HEALTHCARE COMPLIANCE MATTERS**

The Company is subject to a number of federal and state healthcare laws that are intended to, among other things, protect the health and well-being of patients that may be candidates for the Company's products. To ensure compliance with these laws, the Company has developed a Corporate Compliance Program, which consists of a series of policies and procedures. You are required to review and comply with these policies and procedures as they relate to your responsibilities within the company and to report any behaviors that may indicate non-compliance with such laws and/or the Company's Corporate Compliance Program. Copies of all Company policies and procedures are available on the Company intranet website.

(a) Interactions with Health Care Professionals. The federal Anti-Kickback Statute prohibits the offering of anything of value that is intended to influence a person to recommend, prescribe or purchase a product (including prescription medication) that may be reimbursed by the government (e.g., Medicare or Medicaid). The Company is committed to complying with these laws. Certain interactions with health care professionals and programs offered by the Company, including but not limited to speaker programs, consulting arrangements, and support for scientific and educational activities, need to be reviewed to ensure compliance with these laws. The Company's Corporate Compliance Program is consistent with the Code on Interactions with Healthcare Professionals adopted by the Pharmaceutical Research Manufacturers of America (PhRMA Code) and the Office of Inspector General's Compliance Program for Pharmaceutical Manufacturers (OIG Guidelines). If you are involved in commercial activities on behalf

of the Company, you must comply with all Company policies and procedures with respect to interactions with health care providers.

(b) Product Information and Marketing. **The Company is committed to facilitating the safe, effective, and knowledgeable use of our products consistent with the approved prescribing information, and to providing truthful, non-misleading information to physicians and patients that is supported by scientific evidence. We are also committed to abiding by the laws and regulations that apply to advertising and promotion of our products, including rules of the FDA and other regulatory authorities. If you are engaged in sales and marketing activities, you must comply with all Company policies and procedures with respect to promotional activities.**

(c) Product Complaints and Adverse Events. **Any employee, officer or director that becomes aware of a product complaint or adverse reaction to a Company product is required to report the information immediately to the Company's Chief Medical Officer in accordance with Company policy.**

* * *

(e) The False Claims Act. **In cases of reimbursement for pharmaceutical products under a federal health care program, such as Medicare and Medicaid, the federal government considers the promotion of an unapproved drug or an unapproved use of an approved drug to be a false claim against the government and unlawful. Similarly, the provision of a kickback in connection with the promotion of the product is a violation of the False Claims Act. If you are engaged in sales and marketing activities, you must comply with all Company policies and procedures with respect to promotional activities.**

20. **REPORTING ILLEGAL OR UNETHICAL BEHAVIOR**

(a) You are encouraged to talk to supervisors or members of management about observed illegal or unethical behavior or when in doubt about the best course of action in a particular situation. If you report illegal or unethical behavior to a supervisor or a member of management, the individual receiving the complaint has an affirmative duty to report that information to the Company's Compliance Officer (or the Chief Executive Officer if the complaint relates to the Compliance Officer). It is the policy of the Company not to allow retaliation for reports of misconduct by

others made in good faith by employees. You are expected to cooperate in internal investigations of misconduct.

* * *

21. **PERSONAL RESPONSIBILITY AND COMPLIANCE PROCEDURES**

* * *

(b) The Compliance Officer or such other person as is designated by the Company's Board of Directors shall be responsible for ensuring that the Code becomes an integral part of the Company's culture (the "Ethics Manager"). The Company shall ensure that all employees have access to the Code on the Company's internal website and shall provide each employee with a hard copy of the Code upon request. The Company will take such actions as it deems necessary to promote high standards of ethical conduct and to instruct employees regarding improper or illegal conduct. The Company shall maintain a record of all incidents reported as violations of this Code, and the Ethics Manager shall provide the Board of Directors on at least a quarterly basis a report summarizing all communications expressing complaints or concerns received and all actions taken by the Company in response thereto.

* * *

(e) **The Ethics Manager together with the Company's Compliance Committee shall be responsible for implementing the appropriate disciplinary action in accordance with the Company's policies and procedures for any employee who is found to have violated the Code. The Chairman of the Board of Directors shall be responsible for implementing the appropriate disciplinary action for any officer or director who is found to have violated the Code.** The Ethics Manager shall ensure that the disciplinary mechanisms described in this section shall be subject to annual review by the Board of Directors. In addition to imposing discipline upon persons involved in non-compliant conduct, the Company also shall impose discipline, as appropriate, upon individuals who fail to detect non-compliant conduct and upon individuals who fail to report known non-compliant conduct. Disciplinary action may include the termination of the employee's employment. Disciplinary action shall be documented, as appropriate.

(f) **In the event of a violation of the Code, the Ethics Manager or the Chairman of the Board of Directors, as applicable, should assess the situation to determine whether the violation demonstrates a problem that requires remedial action as to Company policies and procedures. Such remedial action may include retraining Company employees, modifying Company policies and procedures, improving monitoring of compliance under existing procedures and other action necessary to detect similar non-compliant conduct and prevent it from occurring in the future**. Such corrective action shall be documented, as appropriate.

50. Vanda's directors, officers and employees are also subject to Vanda's Comprehensive Compliance Program:

Overview of Vanda's Compliance Program

2. Leadership and Structure

Compliance Officer

Vanda has appointed a Chief Compliance Officer ("Compliance Officer") who is responsible for the operation and oversight of the Company's Compliance Program. **The Compliance Officer's responsibilities include, among other things, developing policies and procedures, training employees on the Compliance Program, addressing allegations of non-compliance, and implementing appropriate remedial measures where applicable. As appropriate, the Compliance Officer reports compliance-related issues directly to the Chief Executive Officer and/or the Board of Directors**.

Compliance Committee

Vanda has organized a Compliance Committee that consists of the Vanda senior management team. The Compliance Committee meets regularly to advise and assist the Compliance Officer in the administration of the Compliance Program.

3. Education and Training

Vanda's directors, officers, and employees are expected to comply with the Compliance Program, the Code of Business Conduct, and all written policies and procedures. A central aspect of the Company's Compliance Program is educating and training employees on their legal and ethical obligations under applicable laws, regulations, and

Company policies. All new employees must complete initial compliance training as part of new hire orientation, and additional compliance training as new developments in applicable laws, regulations, or policies and procedures arise.

4. Internal Lines of Communication

Employees are responsible for ensuring that Vanda's policies and procedures are met. This obligation requires that employees (1) seek compliance guidance when unclear about an ethical situation or specific conduct, and (2) report possible violations of laws, regulations, or Company policies. Vanda's policies provide for confidential reporting of allegations of misconduct and protections against retaliation for such reporting. Employees should contact their supervisor, the Compliance Officer, Senior Management, or Human Resources regarding questions about the Compliance Program or to report potential violations. Employees may also report potential violations anonymously. The Company has set up a compliance hotline number that can be used for these anonymous reports.

5. Auditing and Monitoring

Vanda's Compliance Program includes efforts to audit, monitor, and evaluate compliance with the Company's compliance policies and procedures. The nature, extent, and frequency of compliance monitoring and auditing varies according to a variety of factors, including new regulatory requirements, changes in business practices, and other considerations.

6. Disciplinary Standards

Adherence to the Company's Code of Business Conduct and policies and procedures is a condition of employment at Vanda. **The Company investigates potential violations of law or Company policy and, where appropriate, implements corrective measures to prevent, detect and deter future violations. Any violation of these requirements by directors, officers, or employees is subject to disciplinary action up to an including termination.**

7. Responding to Potential Violations

A Compliance Program designed in accordance with the OIG Guidance is intended to increase the likelihood of preventing, or at least detecting, unlawful and unethical behavior. Even an effective Compliance Program, however, may not prevent all violations. **As**

> **such, Vanda investigates potential violations of law or Company policy and, where appropriate, implements corrective measures to prevent, detect and deter future violations.**

51. Defendant Watkins is Chairman of the Board and Chairman of the Nominating/Corporate Governance Committee. Defendant Dugan is a member of that committee. As such, Defendants Watkins and Dugan were required to comply with the Nominating/Corporate Governance Committee Charter that was in place at the time of the alleged wrongdoing. The Nominating/Corporate Governance Committee Charter provides that each director serving on the committee is responsible for (i) overseeing the nomination of directors to the Board and its committees and other related matters; (ii) overseeing the evaluation of the Board; (iii) reviewing and considering developments in corporate governance practices; and (iv) recommending to the Board a set of effective corporate governance policies and procedures for the Company.

52. The Nominating/Corporate Governance Committee Charter further provides that the committee's responsibilities include, among other things:

> **Duties and Powers**
>
> * * *
>
> *Board and Committee Nomination and Evaluation*
>
> * * *
>
> 5. **Monitoring compliance with Board and Board committee membership criteria and developing and overseeing a Board performance evaluation process and evaluating at least annually the performance and effectiveness of the Board, including conducting surveys of director observations, suggestions and preferences, and discussing the results of such process with the Board.**
>
> 6. Evaluating and, if deemed necessary, making recommendations on the removal of any Board member in accordance with the Code of

Business Conduct and Ethics or the Guidelines, for cause or for other appropriate reason.

* * *

Corporate Governance

1. **Regularly reviewing issues and developments related to corporate governance and identifying and bringing to the attention of the Board current and emerging corporate governance issues and developments that may affect the business operations, performance or public image of the Company.**

2. Evaluating at least annually the performance by management, the Board and each Board committee of their duties and responsibilities relating to corporate governance under the Company's Code of Business Conduct and Ethics, the Guidelines and the rules of Nasdaq and the SEC.

* * *

6. Conducting a preliminary review of director independence and making recommendations to the Board relating to such matters.

7. Reviewing the disclosures included in the Company's annual proxy statement regarding the Company's director nomination process and other corporate governance matters.

Resources and Authority

The Committee may conduct or authorize investigations into or studies of matters within the Committee's scope of responsibility with full access to all books, records, facilities and personnel of the Company.

The Committee shall have the authority to engage outside legal, accounting or other advisors, as it determines necessary to carry out its duties. The Committee shall have sole authority to approve related fees and retention terms, and the Company shall provide the Committee with adequate funding to allow the Committee to perform its duties under this Charter.

53. Defendant Dugan is Chairman of the Audit Committee. Defendants Cola and Milano are former members of that committee. As such, Defendants Dugan, Cola, and Milano

were required to comply with the Audit Committee Charter that was in place at the time of the alleged wrongdoing. The primary purpose of the Audit Committee is to provide oversight of (i) the quality and integrity of the Company's financial statements and other financial information provided by the Company to its stockholders; (ii) the Company's retention of its independent accountants, including oversight of the terms of their engagement and their performance, qualifications, and independence; (iii) the effectiveness of the Company's internal and disclosure controls; and (iv) the Company's compliance with its ethics policies and legal and regulatory requirements. The Audit Committee's Charter also places responsibility on the Audit Committee for preparing the report on this compliance for inclusion in the Company's annual proxy statement as required by SEC rules.

54. The Audit Committee is required to meet at least once quarterly and at least annually with the Company's Chief Financial Officer, the independent accountants and, to the extent applicable, internal auditors. The Audit Committee is responsible for monitoring the Company's information and reporting systems to track the Company's compliance with the statutes and regulations.

55. The Audit Committee Charter further provides that the Audit Committee's responsibilities include, among other things:

> **Duties and Powers**
>
> * * *
>
> Financial Statements, Controls and Reports
>
> 11. Review and approve, if applicable, a timely analysis from management relating to any significant proposed or contemplated changes to the Company's accounting principles, policies, estimates, internal controls, disclosure controls, procedures, practices and internal auditing plans (including those policies for which management is required to exercise discretion or judgments regarding the implementation thereof).

12. Review disclosures made to the Committee by the Company's Chief Executive Officer and Chief Financial Officer during the certification process for the Company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q about any significant deficiencies or material weaknesses in the design or operation of internal controls or material weaknesses therein and any fraud involving management or other employees who have a significant role in the Company's internal controls, as contemplated by the Company's disclosure policies in effect from time to time.

13. Discuss with the Company's independent accountants their annual audit plan, including the scope of audit activities and all critical accounting policies and practices to be used, and any other matters required to be discussed by applicable requirements of the PCAOB or other applicable rules, regulations or laws.

14. Periodically discuss with the Company's independent accountants, without management being present, (a) their judgments about the quality, appropriateness and acceptability of the Company's accounting principles and financial disclosure practices, as applied in its financial reporting; (b) the completeness and accuracy of the Company's financial statements; and (c) such matters as are required to be discussed with the Committee under generally accepted auditing standards.

15. Review the Company's annual and quarterly consolidated financial statements with management and the independent accountants prior to the first public release of the Company's financial results for such year or quarter and review any "pro forma" or "adjusted" non-GAAP information included in such release. With the consent of the Committee, the Chair of the Committee may represent and act on behalf of the entire Committee for purposes of the review of any quarterly consolidated financial statements.

16. Review the Company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q in advance of such filings. With the consent of the Committee, the Chair of the Committee may represent and act on behalf of the entire Committee for purposes of the review of any Quarterly Reports on Form 10-Q.

17. Review the Company's accounting treatment of tax related matters, the presentation of tax matters in the footnotes of the financial statement, its compliance with applicable tax laws and regulations and any decisions by management regarding tax planning.

18. Meet periodically with management and/or the independent accountants to:

- review the annual audit plans of the independent accountants;
- discuss any significant matters arising from any audit or report or communication relating to the consolidated financial statements, including any material audit problems, disagreements or difficulties and responses by management;
- understand the significant judgments made and alternatives considered in the Company's financial reporting, including the appropriateness of the alternatives ultimately chosen; and
- discuss policies with respect to significant financial risks and exposures, if any, and the steps taken to assess, monitor and manage such risks.

21. Review with management, the Company's independent accountants and, to the extent applicable, the internal auditors (or other persons responsible for the Company's internal audit function): (a) the results of the annual audit of the Company and the independent accountants' procedures with respect to interim periods, including any significant findings, comments or recommendations of the independent auditors and, to the extent applicable, internal auditors (or other persons responsible for evaluating the Company's compliance with internal controls) together with management's responses thereto; and (b) any significant changes in the Company's accounting principles or the methods of applying the Company's accounting principles.

22. Review with the Company's external counsel any legal matters that could have a significant impact on the Company's financial statements, the Company's compliance with applicable laws and regulations and inquiries received from regulators or governmental agencies.

23. Review the reports prepared by management, and attested to by the Company's independent accountants, assessing the adequacy and effectiveness of the Company's internal controls and procedures, prior to the inclusion of such reports in the Company's periodic filings as required under the rules of the SEC; the Committee will also meet separately with the independent accountants, with and without management present, to discuss the results of their examination.

<u>Reporting and Recommendations</u>

24. Direct the Company's independent accountants to review, before filing with the SEC, the Company's interim financial statements included in quarterly reports on Form 10-Q, using professional standards and procedures for conducting such reviews.

25. Determine, based on the reviews and discussions noted above, whether to recommend to the Board that the audited financial statements be included in the Company's Annual Report to Stockholders and on Form 10-K for filing with the SEC.

26. Prepare any report, including any recommendation of the Committee, required by the rules of the SEC to be included in the Company's annual proxy statement.

27. Maintain minutes or other records of meetings and activities of the Committee.

28. Report the Committee's activities to the Company's CEO and the Board on a regular basis, including with respect to any issues that arise regarding the quality or integrity of the Company's financial statements, the effectiveness of the Company's internal controls or disclosure controls, the performance and independence of the Company's independent accountants and any other issue that the Committee believes should be brought to the attention of the Board. Such reports may be made orally or in writing.

Other Responsibilities

29. Overseeing compliance with the disclosure requirements of the SEC, including disclosure of information regarding auditors' services, audit committee members, member qualifications and services.

30. Establish and maintain procedures for (a) the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls and auditing matters and business conduct or ethics violations and (b) the confidential, anonymous submission by employees of the Company of concerns

* * *

32. Review and provide prior approval of all transactions or arrangements required to be disclosed pursuant to SEC Regulation S-K, Item 404, between the Company and any of its directors, officers, principal stockholders or any of their respective affiliates, associates or related parties.

* * *

36. **Review the Company's compliance with applicable business ethics regulations and its Code of Business Conduct and Ethics, as amended or restated from time to time, and review complaints made pursuant to the Company's Whistleblower Policy in accordance with such policy as amended or restated from time to time.**

37. Performing such other duties as may be necessary or desirable to comply with the applicable laws, rules and regulations promulgated under the Sarbanes-Oxley Act, or by the SEC, Nasdaq or any other applicable governmental or regulatory agency, if such duties are customarily assigned to the Committee, or requested by the Board.

56. In violation of the Charter and their duties as members of the Audit Committee, defendants Dugan, Cola, and Milano conducted little, if any, oversight of the Company's internal controls over public disclosures, resulting in the dissemination of materially false and misleading statements regarding the Company's business, operational and compliance policies. Further, defendants Dugan, Cola, and Milano consciously disregarded their duties to monitor such controls over reporting. The Audit Committee members' failure to perform their duties in good faith resulted in misrepresentations to the SEC, the investing public, and the Company's shareholders.

57. In addition, as executive officers and directors of a publicly-traded company, the common stock of which was registered with the SEC pursuant to the Exchange Act and traded on NASDAQ, the Defendants had a duty not to effect the dissemination of inaccurate and untruthful information with respect to the Company's financial condition, performance, growth, operations, financial statements, business, products, management, earnings, internal controls, and present and future business prospects, so that the market price of the Company's common stock would be based upon truthful and accurate information. Accordingly, the Defendants breached their fiduciary duties by knowingly or recklessly causing Vanda to make false and misleading statements of material fact

about the Company's financial, internal controls and compliance with applicable rules and regulations.

58. Each of the Defendants further owed to Vanda and its shareholders the duty of loyalty requiring that each favor Vanda's interest and that of its shareholders over their own while conducting the affairs of the Company and refrain from using their position, influence, or knowledge of the affairs of the Company to gain personal advantage.

SEC REQUIREMENTS

59. SEC Regulation S-K requires that every Form 10-Q and Form 10-K filing contain "Management's Discussion and Analysis of Financial Condition and Results of Operations" ("MD&A"), drafted in compliance with Item 303 of Regulation S-K, 17 C.F.R. §229.303. The MD&A requirements are intended to provide material historical and prospective disclosures that enable investors and others to assess the financial condition and results of a company's operations, with emphasis on the company's prospects for the future.

60. Item 7 of Form 10-K and Item 2 of Form 10-Q require that a company's SEC filings furnish the information required under Item 303(a)(3) of Regulation S-K, which in turn requires that the MD&A section of a company's filings with the SEC, among other things:

> (i) Describe any unusual or infrequent events or transactions or any significant economic changes that materially affected the amount of reported income from continuing operations and, in each case, indicate the extent to which income was so affected. In addition, describe any other significant components of revenues or expenses that, in the registrant's judgment, should be described in order to understand the registrant's results of operations.
>
> (ii) Describe any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations. If the registrant knows of events that will cause

> a material change in the relationship between costs and revenues (such as known future increases in costs of labor or materials or price increases or inventory adjustments), the change in the relationship shall be disclosed.

61. The instructions for Item 303(a)(3) state that "[t]he discussion and analysis [section] shall focus specifically on material events and uncertainties known to management that would cause reported financial information not to be necessarily indicative of future operating results or of future financial condition."

SUBSTANTIVE ALLEGATIONS

A. Background

62. Vanda is a biopharmaceutical company that focuses on the development and commercialization of drugs for the treatment of central nervous system disorders.

63. Vanda was co-founded by defendant Polymeropoulos in 2003 after he left Novartis AG ("Novartis"). Vanda became a publicly-traded company on April 18, 2006.

64. The Company is incorporated in Delaware with its headquarters in Washington, D.C. The Company owns and markets the drugs Fanapt and Hetlioz.

65. **Fanapt** is a medication used to treat schizophrenia in adults that was approved by the FDA in 2009, when the drug was marketed by Novartis. In December 2014, Vanda took over Fanapt's marketing.

66. The approved FDA label for Fanapt states:

> FANAPT is an atypical antipsychotic agent indicated for the acute treatment of schizophrenia in adults. In choosing among treatments, prescribers should consider the ability of FANAPT to prolong the QT interval and the use of other drugs first. Prescribers should also consider the need to titrate FANAPT slowly to avoid orthostatic hypotension, which may lead to delayed effectiveness compared to some other drugs that do not require similar titration.

67. **Hetlioz** is a circadian regulator approved *only* to treat Non-24. Hetlioz purportedly resets the master body clock and aligns it with the 24-hour day. On January 19, 2010, the FDA granted Hetlioz orphan drug designation status for Non-24 in blind individuals without light perception.[9]

68. On January 31, 2014, Vanda announced that the FDA had approved Hetlioz 20 mg capsules for the treatment of Non-24.

69. The prescriptions for both Fanapt and Hetlioz are reimbursable under federal health care programs, including Medicare, Medicaid, and Tricare.

70. On April 12, 2012, Vanda entered into a license agreement with Eli Lilly, which granted Vanda an exclusive worldwide license to develop and commercialize VLY-686 (tradipitant). During the Relevant Period, tradipitant was undergoing clinical trial testing for the purpose of obtaining FDA approval, but is not currently FDA-approved.

B. <u>Vanda Derives its Revenues Solely from Sales of Fanapt and Hetlioz</u>

71. According to the 2015 Form 10-K (defined below), Vanda's "net product sales consist of sales of HETLIOZ® and sales of Fanapt®." During the Relevant Period, there were no other contributors to Vanda's revenue other than the sales of Fanapt and Hetlioz.

72. During fiscal year 2015 ("FY15"), Vanda generated $109.925 million in revenue, of which sales of Fanapt constituted $65.623 million and sales of Hetlioz constituted $44.302 million.

[9] An "orphan drug" is one that is developed to treat medical conditions which, because they are so rare, would not be profitable to produce without government assistance.

73. During fiscal year 2016 ("FY16"), Vanda generated $146.017 million in revenue, of which sales of Fanapt constituted $74.346 million and sales of Hetlioz consisted of $71.671 million in revenue.

74. During fiscal year 2017 ("FY17"), Vanda generated $165.083 million in revenue, of which sales of Fanapt constituted $75.105 million and sales of Hetlioz constituted $89.978 million.

75. During the fiscal year ended December 31, 2018, Vanda generated $193.118 million in revenue, of which sales of Fanapt constituted $77.283 million and sales of Hetlioz constituted $115.835 million.

76. Accordingly, during the Relevant Period, marketing and selling Fanapt and Hetlioz represented the core of Vanda's operations and financial performance.

C. The Regulatory Scheme: the False Claim Act, State False Claim Acts, and the FD&C Act

77. The term "off-label marketing" or "off-label promotion" refers to marketing or promoting a drug for an indication (a disease or symptom) that it has never received FDA approval to treat.

78. The FDA only approves drugs if they have been shown to be safe and effective for the specific indications that they are approved to treat. However, the FDA does not regulate or control how FDA-approved drugs are prescribed by physicians after the drugs have been approved. Thus, physicians are able, on their own volition, to prescribe drugs for off-label uses.

79. The law requires pharmaceutical companies to comply with the FD&C Act and related FDA regulations, which prohibit pharmaceutical companies from introducing drugs into interstate commerce for any intended use that the FDA has not determined to be safe and

effective. This means that it is illegal for a company or its management to actively market or promote drugs for off-label uses.

80. Thus, Vanda was legally prohibited from engaging in off-label marketing or promotion during the Relevant Period. The FD&C Act and the FDA also prohibit pharmaceutical companies, like Vanda, from introducing misbranded drugs into interstate commerce. Importantly, FDA guidance requires that if a physician asks a pharmaceutical company sales representative about potential off-label uses for a drug, the sales representative "should refer such questions to a medical/scientific officer or department … and the officer or department to which the referral is made should be separate from the sales and/or marketing department."

81. As set forth herein, Vanda disregarded FDA guidance during the Relevant Period. Instead, Vanda trained and incentivized its sales representatives to market and sell Fanapt and Hetlioz for off-label uses.

82. In recent years, off-label drug promotion has become the focus of health care fraud enforcement efforts by federal and state authorities under the FCA and corresponding state false claims statutes. In FCA cases, which often start as qui tam whistleblower complaints, off-label promotion for non-FDA approved indications allows federal and state governments to recover large monetary settlements (including treble damages) from drug companies for each instance of off-label promotion. Accordingly, at all times during the Relevant Period, any and all off-label promotion or marketing engaged in by Vanda violated the FD&C Act, the FCA, FDA guidance and regulations, and state false claims statutes.

83. Since at least November 2015, Vanda engaged in a scheme to promote Fanapt and Hetlioz for off-label uses, in addition to several other prohibited promotional strategies. Specifically, Vanda: (i) promoted Fanapt for uses other than treating schizophrenia, the drug's

sole indication; (ii) promoted Fanapt off-label to pediatric patients despite the drug being approved only for adults; (iii) overstated Fanapt's efficacy to providers; (iv) made false and misleading statements regarding Fanapt's safety warnings; (v) downplayed the safety risks associated with Fanapt; (vi) improperly provided titration packets[10] which was in violation of the FDA-approved titration schedule and did not have adequate instructions for use; (vii) promoted Fanapt as a first line therapy; (viii) misused Fanapt copay cards; and (ix) promoted Hetlioz for off-label uses.

84. The costs of the prescriptions for these two drugs were reimbursed by government health care programs, including Medicare, Medicaid and Tricare. Accordingly, the government was defrauded because of Defendants' misconduct.

D. Vanda Obtains a License to Market and Sell Fanapt

85. In June 2004, before Vanda went public, the Company entered into a sublicense agreement with Novartis to develop and commercialize Fanapt on behalf of Novartis.

86. When Vanda went public in April 2006, the Company explained to investors that it believed Fanapt would be effective in treating both schizophrenia and bipolar disorder. Specifically, the Company stated in the Form 424B4 prospectus provided to investors, in pertinent part, that:

> In addition to schizophrenia, we believe iloperidone [Fanapt] may be effective in treating bipolar disorder. Most of the approved atypical antipsychotics have received approval for bipolar disorder subsequent to

[10] Drug titration is the process of adjusting the dose of a medication for the maximum benefit without adverse effects. When a drug has a narrow therapeutic index, titration is especially important, because the range between the dose at which a drug is effective and the dose at which side effects occur is small. Some examples of the types of drugs commonly requiring titration include insulin, anticonvulsants, blood thinners, anti-depressants, and sedatives.

> commercialization for the treatment of schizophrenia. Iloperidone is ready for an initial Phase II trial in bipolar disorder.

87. Most antipsychotics – the drugs that Fanapt would directly compete with – are indicated for treating multiple related mental illnesses such as schizophrenia *and* bipolar disorder.

88. Because bipolar disorder is more than twice as prevalent in the United States as schizophrenia, securing approval for Fanapt to treat bipolar disorder would vastly expand the pool of potential patients who could be prescribed Fanapt on-label.

89. If Fanapt were approved only for treating schizophrenia, it would be at a significant competitive disadvantage.

90. Despite the commercial importance of getting FDA approval for Fanapt to treat multiple related mental illnesses, Vanda only submitted a new drug application ("NDA") for Fanapt to treat schizophrenia, and ***not*** for bipolar disorder or any other psychological disorder. According to Vanda's Form 10-Q dated May 11, 2009, Vanda submitted the NDA for Fanapt on September 27, 2007.

91. In May 2009, the FDA approved Fanapt to treat *only* schizophrenia in adults. The FDA did not grant approval for the treatment of bipolar disorder, any other mental illness, or even schizophrenia in adolescents or children. For this reason, Fanapt's FDA label states that it is approved only to treat "adults with schizophrenia."

92. Fanapt's FDA label explicitly states that Fanapt is approved as a second line treatment, which defendant Polymeropoulos acknowledged during the Jefferies Healthcare Conference held on June 9, 2016 (the "6/9/16 Conference") and the Oppenheimer Healthcare Conference held on March 21, 2017 ("3/21/17 Conference").

93. Fanapt's approval as a second-line treatment meant that Fanapt was *only* to be prescribed if a different antipsychotic had already been used by a patient and was shown to be ineffective or poorly tolerated.

94. The reason the FDA approved Fanapt as a second line treatment was because Fanapt users have a serious risk of developing QT prolongation, a serious side effect which can result in sudden death.

95. Accordingly, Fanapt's FDA label contains a "black box" warning stating that other antipsychotics should be tried first. A "black box" warning appears on FDA labels to alert patients and doctors about serious adverse effects or life-threatening risks for a particular drug. According to the FDA, a "black box" warning is the most serious drug warning that the FDA can impose on a drug. At all relevant times, Fanapt carried a "black box" warning due to its risk of causing QT prolongation.

96. There were additional restrictions. Specifically, Fanapt was approved by the FDA for a "recommended target dosage" of "12 to 24 mg/day administered twice daily." Fanapt's requirement to be taken twice-daily made it unlike most other antipsychotics, which are indicated by the FDA for once-daily treatment. The reason that most antipsychotics have a once-daily formulation is because patients with mental disorders have difficulty taking their medicine on a routine schedule. Prescribing mentally ill patients medicine that only requires once a day dosage increases the chances the patient will take their medicine as scheduled.

97. After Fanapt received FDA approval, Vanda and Novartis entered into an amended sublicense agreement in October 2009 that gave Novartis exclusive commercialization rights to Fanapt. Thus, as of October 2009, Novartis was responsible for selling and marketing

Fanapt in the United States. In return, Vanda received royalty payments from Novartis on sales of Fanapt.

98. In May 2014, Vanda commenced arbitration against Novartis related to the licensing of Fanapt, which was settled in December 2014.

99. Under the terms of the settlement agreement, Vanda obtained the rights to market and sell Fanapt in the United States. Accordingly, while Vanda began marketing and selling Fanapt in the United States for the first time in early 2015, Fanapt had been an FDA approved drug and sold by Novartis since May 2009. Assuredly, losing the right to sell and market Fanapt was not a major loss for Novartis given that after a strong start in January 2010 in which it generated $21 million in revenue, Fanapt's sales collapsed to just $700,000 in the second quarter. Upon information and belief, Defendants hatched their fraudulent scheme described below because they knew that the approved market for Fanapt was insufficient for the drug to be commercially viable.

E. Vanda's Promotion of Fanapt for Off-Label Uses

100. As soon as Vanda began to sell Fanapt in early 2015, the Defendants engaged in a scheme to market and sell Fanapt for off-label use. They did so because, upon information and belief, Fanapt had limited utility, potentially life-threatening risks, and a highly limited patient class The Defendants conducted this scheme because Fanapt was a difficult antipsychotic to sell on-label due to its limited indication (adults with schizophrenia), its status as a second line treatment, its risk for causing QT prolongation (in a black box warning), and its need to be taken twice-daily as opposed to once-daily.

i. Qui Tam Lawsuit Based on Off-Label Marketing Scheme

101. Richard Gardner ("Gardner") is the relator in the Qui Tam Lawsuit and worked at Vanda as a Regional Business Leader ("RBL") for the mid-west region from November 16, 2015 until August 5, 2016. Gardner's territory included Illinois, Wisconsin, Michigan, Ohio, Western Pennsylvania, West Virginia, and Indiana. Prior to joining Vanda, Gardner worked in the pharmaceutical industry for over 23 years, including ten years at Pfizer / Pharmacia where he served as Regional Sales Trainer, Corporate Sales Trainer, and District Manager. Gardner believes that his departure from Vanda was due to his reluctance to play along with Vanda's off-label marketing promotion scheme for Fanapt and Hetlioz.

102. Gardner filed the Qui Tam Lawsuit against Vanda on March 10, 2017, alleging violations of the FCA and analogous false claims statutes of twenty-eight States and the District of Columbia. The Qui Tam Lawsuit is currently pending.

103. According to Gardner, RBLs were in charge of overseeing Vanda's 50 sales representatives for Fanapt, who were independent contractors hired through Publicis Touchpoint Solutions. Gardner states there were five RBLs during the Relevant Period, including himself and Jeff Bourgeois ("Bourgeois"). Bourgeois was an RBL at Vanda from November 2015 until June 2018, where he managed the Vanda sales representatives in his territory promoting Fanapt and Hetlioz. When Bourgeois was hired, his territory consisted of Louisiana, Arkansas, and Texas. In early 2017, Bourgeois' territory was changed to Texas and Oklahoma.

104. According to Gardner, RBLs reported directly to Vanda's National Sales Director, who was David James ("James") from January 2014 until July 2016. Vanda's National Sales Director reported directly to Vanda's CCO, meaning initially to non-party Gibbs and then after December 2015, to defendant Reverberi. Vanda's CCO reported directly to Vanda's CEO, defendant Polymeropoulos. According to Gardner, the RBLs participated in weekly conference

calls with James and Paul Ramirez ("Ramirez"), an attorney and Head of Sales, to discuss the marketing and promotion of Fanapt and Hetlioz, which defendant Polymeropoulos would periodically join. According to Gardner, several times per year the RBLs would also attend in-person meetings with defendant Polymeropoulos and other Vanda senior executives in Washington, D.C.

105. When Vanda began marketing and selling Fanapt in early 2015, it only had 12 sales representatives covering the drug. These 12 sales representatives were termed the "Fanapt 12" by defendant Polymeropoulos.

106. The Fanapt 12 were focused on selling Fanapt to psychiatrists in New York City and St. Louis and were overseen by one RBL.

107. The Defendants decided to expand the sales force for Fanapt in November 2015 to increase the Company's footprint throughout the United States. To that end, in November 2015, Vanda hired: Gardner; Bourgeois; two other RBLs; 9 new sales representatives; and promoted one of the Fanapt 12 to RBL. This brought the sales team for Fanapt to 50 sales representatives and six RBLs as of November 2015. These 50 sales representatives were termed the "Fanapt 50" by defendant Polymeropoulos.

108. The six RBLs reported directly to James. James reported directly to the CCO (non-party Gibbs and then defendant Reverberi).

109. In addition, according to Gardner and Bourgeois, before the Relevant Period, Vanda hired Ramirez as a consultant to assist James with promoting and selling Fanapt. According to Gardner and Bourgeois, Ramirez worked for Vanda at least until June 2018.

110. According to Gardner and Bourgeois, Ramirez was hired directly by defendant Polymeropoulos to serve as his personal consultant. Gardner and Bourgeois understood that

Vanda specifically structured Ramirez's role with the Company so as to not have a formal employment relationship. Nonetheless, according to Gardner and Bourgeois, Ramirez reported directly to defendant Polymeropoulos and maintained an office in the Company's Washington, D.C. headquarters.

111. The Fanapt 50, the RBLs, and Vanda senior management attended a five-day national Fanapt launch meeting from November 30, 2015 to December 4, 2015, at the Fairmount Hotel in Washington, D.C. (the "November 2015 Meeting").

112. According to Gardner, the following members of Vanda's senior management were in attendance at the November 2015 Meeting: defendants Polymeropoulos, Kelly, and Reverberi and non-parties Gibbs, James, and Ramirez.

113. According to Gardner, Vanda's senior management conducted Fanapt sales training at the November 2015 Meeting. Fanapt was a difficult drug for the Fanapt 50 to market and sell on-label. One of the main reasons is because Fanapt's competitor drugs were indicated to treat not only schizophrenia, but also other related mental illnesses such as bipolar disorder. Fanapt, however, was only approved to treat schizophrenia, only in adults, and was burdened with a black box warning.

114. Nonetheless, at the November 2015 Meeting, Vanda's senior management trained its Fanapt sales force to market and sell Fanapt off-label for mental illnesses other than schizophrenia, especially bipolar disorder. According to Gardner and Bourgeois, the Fanapt 50 were trained at the November 2015 Meeting to promote and sell Fanapt regardless of the underlying condition it was being prescribed to treat.

115. According to Gardner, during the November 2015 Meeting, defendant Polymeropoulos told the Fanapt 50 and the RBLs that, because it was very difficult to get

schizophrenia drugs approved by the FDA, doctors would understand that if Fanapt was approved to treat schizophrenia then it would also be effective in treating other mental health disorders, including bipolar disorder and depression.

116. According to Bourgeois, Vanda's sales force for Fanapt was trained to convince doctors that Fanapt was just as effective as other antipsychotics that treat both schizophrenia and bipolar disorder, regardless of its labeling status.

117. According to Gardner, Fanapt sales representatives were trained to avoid the subject of Fanapt being indicated only for schizophrenia. Gardner recounts that the sales aid for Fanapt distributed by Vanda to its sales representatives (the "Fanapt Sales Aid") specifically directed the sales representatives to push Fanapt even if a doctor stated that he or she does not have schizophrenia patients.

118. According to Gardner, who retained a copy of the Fanapt Sales Aid that is referenced in the Qui Tam Lawsuit pleadings, the Fanapt Sales Aid provided the following question and answer scenario as the very first example in the "overcoming objections" section: the doctor objection is "I don't see any/a lot of patients with schizophrenia" and Vanda's preferred response is "You don't see a lot of schizophrenia but you do use atypical antipsychotics, correct?" Gardner recounts that the sales training for the Fanapt sales representatives primarily focused on this portion of the Fanapt Sales Aid.

119. According to Gardner and Bourgeois, during the November 2015 Meeting, the Fanapt sales representatives role-played mock sales calls for Vanda's senior management. On the occasions where the sales representative would fail to mention schizophrenia, Vanda's senior management would not correct the sales representative or instruct him or her to mention the need

to discuss schizophrenia. In fact, according to Gardner and Bourgeois, they felt that avoiding the word schizophrenia was viewed as a positive by Vanda's senior management.

120. According to Gardner, the Fanapt 12 also participated in the November 2015 Meeting. Gardner recounts that the Fanapt 12 described marketing and promoting Fanapt off-label in a manner similar to the training at the November 2015 Meeting for the Fanapt 50.

121. Further, part of Gardner's job at the November 2015 Meeting was to certify that sales representatives were properly trained to sell and promote Fanapt. To that end, Gardner was responsible for meeting with and grading a Fanapt 12 sales representative from New York. During the meeting, Gardner determined that the New York sales representative was engaging in off-label promotion and Gardner refused to certify the sales representative.

122. Thereafter, Gardner recounts that James and Ramirez expressed annoyance at Gardner's decision to not certify the New York sales representative, even after Gardner explained his reasoning. According to Gardner, the New York sales representative went in for testing again at the November 2015 Meeting before James, without Gardner, and the New York sales representative was certified.

123. According to Gardner and Bourgeois, Vanda encouraged its sales representatives to market Fanapt by promoting its relatively low incidence of akathisia, which is a movement disorder characterized by a feeling of inner restlessness that is a common side effect of antipsychotics.

124. According to Gardner and Bourgeois, Vanda improperly used Fanapt's low incidence of akathisia to promote Fanapt off-label for the treatment of non-schizophrenia mental disorders. For example, the Fanapt Sales Aid provided Vanda's preferred response to the doctor objection that "Fanapt has only one indication," as follows:

> I understand that other antipsychotics have more than one indication. Can you think of any of your adult schizophrenia patients who are experiencing inner restlessness, agitation or other treatment-induced movement disorders on their current medication?
>
> *The Fanapt efficacy and tolerability profile, including its placebo-like rate of akathisia make it an option for patients who need to switch from one antipsychotic to another*.

125. According to Gardner and Bourgeois, the point that Vanda sought to impart on its Fanapt sales representatives was that Fanapt should be promoted as an alternative to all antipsychotics, regardless of whether the patient has schizophrenia, because Fanapt reduces the effects of akathisia.

126. To that end, according to Gardner, the Fanapt Sales Aid provided Vanda's preferred responses to the doctor objection that: "I don't see any/a lot of patients with schizophrenia," as follows: "Akathisia is a drug-induced side effect that can necessitate a treatment switch" and "Fanapt offers atypical antipsychotic efficacy with placebo-like rates of Akathisia."

127. According to Gardner and Bourgeois, by shifting the focus to akathisia and away from the doctor's stated concern that Fanapt would not be appropriate for his or her patients because they do not have schizophrenia, Vanda was promoting and marketing Fanapt off-label.

128. According to Bourgeois, defendant Polymeropoulos informed him during the November 2015 Meeting that every patient with akathisia should be on Fanapt.

129. According to Gardner, Vanda's focus on akathisia at the expense of schizophrenia resulted in objections to Vanda's marketing strategy by Kate Holland ("Holland"), Vanda's Vice President of Sales and Marketing from May 2012 to January 2016.

130. According to Gardner, defendant Polymeropoulos asked Holland to alter the marketing strategy for Fanapt to make it more aggressive. According to Gardner, Holland resigned in January 2016 after refusing defendant Polymeropoulos's request.

131. Also departing Vanda around this time was Gibbs, who only started working at Vanda in April 2015. According to the 12/21/15 Form 8-K, Gibbs resigned after only eight months and forfeited his right to any severance or other post-termination benefits typically afforded to departing corporate executives. According to the 12/21/15 Form 8-K, defendant Reverberi immediately replaced Gibbs as Vanda's CCO.

132. Vanda also ensured that Fanapt would be promoted off-label because it trained sales representatives to convince doctors to switch to Fanapt from Risperidone, Latuda and Saphris – competitor antipsychotics that are FDA-approved to treat both schizophrenia and bipolar disorder.

133. According to Gardner and Bourgeois, Vanda senior management set sales goals for the Fanapt 50 based on the total market for antipsychotics without accounting for the fact that competitor drugs treat more indications than only schizophrenia. According to Gardner and Bourgeois, this resulted in the Fanapt 50 having to promote Fanapt off-label in order to meet their sales goals because Fanapt could only treat a small portion of the relevant antipsychotic market on-label.

134. According to Gardner and Bourgeois, the RBLs, defendant Reverberi, and non-parties James, and Ramirez participated in a conference call in June 2016 where, among other things, defendant Reverberi confronted the RBLs for not growing the sales of Fanapt faster. Several RBLs expressed frustration at the fact that Fanapt is FDA approved for only one indication, thereby limiting the pool of potential sales, to which defendant Reverberi responded

"doctors can use Fanapt anywhere they want." Defendant Reverberi warned the RBLs on the call that their failure to increase Fanapt sales would jeopardize their jobs. After the conference call, Gardner and Bourgeois discussed whether defendant Reverberi had threatened them.

135. According to Bourgeois, he participated in a call with defendant Reverberi in June 2018 to discuss the Fanapt 50's inability to grow Fanapt prescriptions at the rate desired by Vanda's senior management. During this meeting, Bourgeois explained to defendant Reverberi that doctors were reporting that insurers were reluctant to pay for it because it was being prescribed off-label. In response, defendant Reverberi told Bourgeois that he did not believe Bourgeois, and asked Bourgeois what his plan was to turn around Fanapt sales.

136. According to Bourgeois, on one occasion in early 2018, Kate Arnold ("Arnold"), Vanda's Head of Compliance from February 2017 to the present, contacted Bourgeois after reviewing his sales representative reports because Bourgeois had written that sales representatives need to "push" doctors to prescribe Fanapt. Bourgeois included this language in his sales representative reports because that is what he was instructed to do by Tom Griffin ("Griffin"), Vanda's Vice President of Sales from 2017 to the present.

137. According to Bourgeois, Griffin was the permanent replacement for James, who departed from Vanda in July 2016. Bourgeois recounts that, like James, Griffin reported directly to defendant Reverberi during the Relevant Period.

138. According to Bourgeois, Arnold asked him to change this language because defendant Polymeropoulos was concerned about being sued by the government. Arnold further stated that Bourgeois was not the only RBL with this issue, and that she had spoken to other RBLs about changing similar language regarding pushing doctors to prescribe Fanapt.

139. According to Bourgeois, during early 2018, defendant Reverberi would inquire about how Bourgeois could get more Fanapt prescriptions from Dr. Boris Rubashkin ("Rubashkin"), a psychiatrist in Houston, Texas. Rubashkin was a large prescriber of Fanapt. Brandy Barrington ("Barrington"), who was employed at Vanda from January 2016 to September 2018, was the Vanda sales representative responsible for interacting with Rubashkin. Bourgeois informed defendant Reverberi that Rubashkin had informed Barrington that he was already using Fanapt in every schizophrenia patient he had in his practice. Nonetheless, defendant Reverberi pushed Bourgeois to find a way to increase Fanapt prescriptions from Rubashkin, even though Bourgeois made it clear that there were no additional schizophrenia patients to add from Rubashkin's practice.

140. Vanda's intent to promote Fanapt off-label is also illustrated by how it compensated the Fanapt 50, which was to pay them on, to use Vanda's terminology, "total dirt." This meant that Vanda paid its sales representatives for every Fanapt prescription written in their territory, regardless of the condition it was written to treat, meaning they were paid for both on-label and off-label sales.

141. On several occasions during his employment with Vanda, Gardner stated to Vanda senior management that incentive compensation should not be based on total dirt and, instead, should only be based on approved call targets, meaning doctors treating adult schizophrenia patients.

142. Gardner made this recommendation because he was concerned that paying sales representatives on total dirt incentivized off-label promotion. In fact, Gardner stated to Ramirez on one occasion that "Vanda is paying for off-label promotion" and "the sales goals are based on illegitimately earned prescriptions." In response, Ramirez warned Gardner not to use the word

"illegitimate" again and told Gardner not to bring up the off-label topic again and not to send Ramirez any emails about paying on total dirt.

143. According to Bourgeois, in a meeting with Griffin and the RBLs in April 2018, the RBLs expressed concern about paying Fanapt sales representatives on total dirt. During this discussion, Griffin stated that the decision to pay on total dirt was made by senior management, and it was not changing.

144. The Defendants knew, or recklessly disregarded, that Fanapt was being promoted off-label because, according to Gardner and Bourgeois, Vanda's senior management had access to information apprising them of the precise volume and percentage of Fanapt sales that were made off-label. According to Gardner, early in his employment at Vanda, he was informed by senior management that the Company received ICD-9 data for each Fanapt prescription.[11] This ICD-9 data consisted of the indication that each Fanapt prescription was written for (the ICD-9 diagnosis code) and the dosage amount (the NDC code). According to Bourgeois, Vanda's senior management would know exactly how many Fanapt prescriptions were being written off-label by viewing the ICD-9 data that the Company routinely received.

145. In addition, Vanda's senior management was informed by at least one Fanapt sales representative that Fanapt prescriptions were being written off-label during the Relevant Period. According to Gardner, in March 2016, Dallas Medenwald ("Medenwald"), a member of the Fanapt 50 who covered the state of Indiana, called Gardner because the Indiana Medicaid program was changing its coverage to no longer reimburse for off-label antipsychotics, resulting in a loss of 400 prescriptions per month in Indiana.

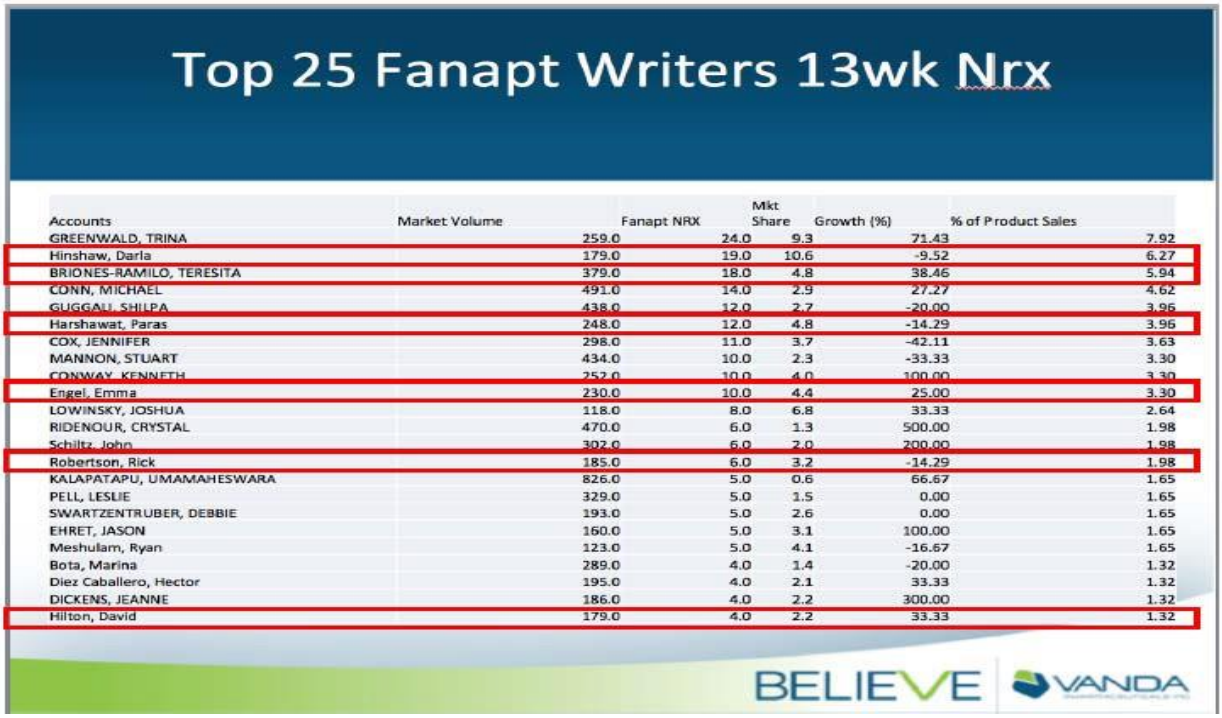
[11] ICD-9 is a list of codes corresponding to diagnoses and procedures that are entered into a patient's electronic health record and are used for diagnostic, billing, and reporting purposes.

146. Vanda also engaged in off-label promotion of Fanapt during the Relevant Period by targeting children with schizophrenia, instead of the adults for whom Fanapt was solely approved by the FDA to treat. According to Gardner, the 400 prescriptions lost by Medenwald in Indiana all came from child psychiatrists who were prescribing Fanapt off-label to pediatric patients. Gardner confirmed that James and Ramirez were told that the reason the 400 lost prescriptions in Indiana were off-label was because they were prescribed to pediatric patients.

147. According to Gardner and Bourgeois, Vanda senior management required each of the Fanapt 50 to target the top 25 prescribers of all antipsychotics in their territory, with instructions to focus their sales efforts on convincing these doctors to prescribe Fanapt.

148. According to Gardner and Bourgeois, these top 25 prescribers were placed in charts by the Company and the charts often included child psychiatrists who, by definition, could not prescribe Fanapt on-label because they did not treat adults.

149. For example, in the complaint in the Qui Tam Lawsuit, Gardner provided the following top 25 chart for Vanda's Indiana territory, with the child psychiatrists highlighted:



Top 25 Fanapt Writers 13wk Nrx

Accounts	Market Volume	Fanapt NRX	Mkt Share	Growth (%)	% of Product Sales
GREENWALD, TRINA	259.0	24.0	9.3	71.43	7.92
Hinshaw, Darla	179.0	19.0	10.6	-9.52	6.27
BRIONES-RAMILO, TERESITA	379.0	18.0	4.8	38.46	5.94
CONN, MICHAEL	491.0	14.0	2.9	27.27	4.62
GUGGALI, SHILPA	438.0	12.0	2.7	-20.00	3.96
Harshawat, Paras	248.0	12.0	4.8	-14.29	3.96
COX, JENNIFER	298.0	11.0	3.7	-42.11	3.63
MANNON, STUART	434.0	10.0	2.3	-33.33	3.30
CONWAY, KENNETH	252.0	10.0	4.0	100.00	3.30
Engel, Emma	230.0	10.0	4.4	25.00	3.30
LOWINSKY, JOSHUA	118.0	8.0	6.8	33.33	2.64
RIDENOUR, CRYSTAL	470.0	6.0	1.3	500.00	1.98
Schiltz, John	302.0	6.0	2.0	200.00	1.98
Robertson, Rick	185.0	6.0	3.2	-14.29	1.98
KALAPATAPU, UMAMAHESWARA	826.0	5.0	0.6	66.67	1.65
PELL, LESLIE	329.0	5.0	1.5	0.00	1.65
SWARTZENTRUBER, DEBBIE	193.0	5.0	2.6	0.00	1.65
EHRET, JASON	160.0	5.0	3.1	100.00	1.65
Meshulam, Ryan	123.0	5.0	4.1	-16.67	1.65
Bota, Marina	289.0	4.0	1.4	-20.00	1.32
Diez Caballero, Hector	195.0	4.0	2.1	33.33	1.32
DICKENS, JEANNE	186.0	4.0	2.2	300.00	1.32
Hilton, David	179.0	4.0	2.2	33.33	1.32

BELIEVE VANDA

150. In addition, Vanda had a competition for the Fanapt 50 called "10 to win," which paid an additional bonus every four to six weeks to the sales representative who had the most new prescription growth from a list of ten physicians in their territory chosen by the sales representatives. According to Gardner and Bourgeois, the "10 to win" lists contained child psychiatrists who, by definition, cannot prescribe Fanapt on-label because they do not treat adults.

151. For example, in the complaints in the Qui Tam Lawsuit, Gardner provided the following "10 to win" chart for Vanda's Indiana territory, with the child psychiatrists highlighted:

10 to Win (Current)

		Fanapt			
Actions Accounts	Market Volume	NRX	Mkt Share	Growth (%)	% of Product Sales
CONN, MICHAEL	495.0	16.0	3.23%	60.00%	19.75%
RIDENOUR, CRYSTAL	463.0	5.0	1.08%	150.00%	6.17%
MANNON, STUART	430.0	10.0	2.33%	0.00%	12.35%
SINGH, SURJIT	423.0	3.0	0.71%	100.00%	3.70%
KHAN, SYED	273.0	1.0	0.37%	-50.00%	1.23%
GREENWALD, TRINA	260.0	21.0	8.08%	40.00%	25.93%
CARTER, MICHELLE	255.0	3.0	1.18%	0.00%	3.70%
CONWAY, KENNETH	254.0	11.0	4.33%	100.00%	13.58%
Robertson, Rick	185.0	8.0	4.32%	33.33%	9.88%
REEF, MARK	184.0	3.0	1.63%	-40.00%	3.70%

BELIEVE VANDA

152. By allowing child psychiatrists to be included in the Company's target lists, Gardner and Bourgeois understood that the Defendants intended for Vanda's sales representatives to promote Fanapt off-label.

153. According to Gardner, who retained copies of the top 25 and "10 to win" charts that are referenced in the complaints in the Qui Tam Lawsuit, these charts were available to everyone in Vanda's senior management and sent to defendant Polymeropoulos.

154. It is reasonable to assume that if senior management knew of Fanapt being prescribed off-label, the members of the Board knew, and condoned, the scheme as well.

ii. False Statements that Fanapt was a First-Line Treatment

155. Another type of off-label promotion that Vanda engaged in during the Relevant Period was to promote Fanapt as a first line treatment despite it only being approved by the FDA as a second line treatment given the risks of QT prolongation.

156. According to Gardner and Bourgeois, during the November 2015 Meeting, defendant Polymeropoulos told the RBLs that if Fanapt were approved in November 2015 that it would be approved as a first line drug. For this reason, the Fanapt 50 received no training on ensuring that the patients being prescribed Fanapt had tried another antipsychotic first. In fact, according to Gardner, defendant Polymeropoulos stated at the November 2015 Meeting that most patients will have tried other drugs before being prescribed Fanapt, meaning sales representative did not need to inquire about it.

157. According to Bourgeois, the fact that Fanapt was a second line treatment was not included in any of the promotional materials provided to Fanapt's sales representatives.

158. Even worse, according to Bourgeois, during a 2017 conference call, Ramirez stated to Fanapt's sales representatives that Fanapt was a "first in class" drug. Bourgeois recounts being confused and concerned by this statement because Fanapt's FDA label clearly describes the drug as a second line treatment.

iii. <u>Downplaying QT Prolongation Risk</u>

159. According to the Qui Tam Lawsuit, sales representatives were taught to use the phrase "placebo-like" when touting Fanapt's purported benign safety profile, even though Fanapt's actual side effect profile was not "placebo-like." Vanda knew that these statements were false. In fact, its own sales materials demonstrate that the side effect rate for Fanapt was higher for almost all side effects than those presented by placebo. In addition, Vanda's marketing materials demonstrate that its messaging that Fanapt was "metabolically neutral," was also false.

160. Vanda senior management also sought to minimize that Fanapt was associated with QT prolongation even though the FDA-mandated label stated that Fanapt is associated with QT prolongation. Vanda trained the sales representatives to minimize the QTc prolongation[12] safety warning by saying that the only reason the competing antipsychotic drugs Latuda or Saphris did not have the same warning was because they were approved years after Fanapt, and, if Fanapt were approved today, it similarly would not have the QT prolongation warning.

161. Notwithstanding the seriousness of QT prolongation as a side effect and Fanapt's black box warning, according to Gardner, the Fanapt Sales Aid instructed sales representatives to downplay this risk, stating, in pertinent part, as follows:

> *If Fanapt was approved today, it would not have received the QTc Interval Prolongation warning*. When the FDA approved Fanapt years ago, there was very little data about QTc Interval Prolongation so it was blown out of proportion. *Now, it is no longer a concern and if Fanapt were approved today it would not have the QTc Prolongation side effect warning*.

162. According to Gardner, at the November 2015 Meeting, sales representatives were trained by defendant Polymeropoulos to tell doctors that the competing antipsychotic drugs Latuda and Saphris do not have QT prolongation warnings because they were approved years after Fanapt and the FDA no longer considers QT prolongation a serious issue.

163. Gardner's contemporaneous notes from a manager meeting he participated in while employed at Vanda confirm that Vanda was training its sales representatives to downplay, or even omit, the risk of developing QT prolongation posed by Fanapt. As stated in the Qui Tam Lawsuit pleadings, these notes stated, in pertinent part, that:

> Any A-Typical launched post Latuda will no longer have QT Prolongation as part of the [package insert] as [the] *FDA realizes [QT prolongation] is*

[12] QTc prolongation refers to "corrected" QT prolongation normalized so that it is based on 60 heartbeats per minute.

> *no long worth noting*. [The number of patients experiencing QT prolongation] are too small to be an issue.

164. According to Bourgeois, Vanda did not address QT prolongation with Fanapt's sales representatives other than defendant Polymeropoulos mentioning at the November 2015 Meeting that it was no longer a relevant concern.

165. By not taking steps to properly train Fanapt's sales representatives on the risk of QT prolongation, and the related designation of Fanapt as a second line treatment, Vanda was promoting Fanapt off-label because sales representatives were promoting it as a first line treatment.

iv. Dosage Misrepresentations

166. Vanda also engaged in off-label promotion of Fanapt during the Relevant Period by training its sales representatives to market Fanapt as a once-daily drug, even though Fanapt's FDA label required Fanapt to be taken twice a day.

167. Fanapt's twice daily usage put it at a disadvantage compared to other antipsychotic medications, such as Risperidone and Latuda, which are once-daily formulations. According to Gardner, doctors prefer once-daily antipsychotics because patients with a mental illness are less likely to stick to a medication schedule that requires multiple doses each day.

168. According to Gardner, during the November 2015 Meeting, defendant Polymeropoulos told the RBLs and the Fanapt 50 that Fanapt should have been approved for a once-daily dosing and "many people have told me that I should go back to the FDA and request approval for QD [once a day] dosing for Fanapt because Fanapt's half-life of 23 1/2 hours is so long."

169. According to Gardner, based on this comment, Vanda's sales representatives were trained to promote Fanapt by stating that its 23 1/2 hour half-life meant that Fanapt could be

prescribed once daily, despite the FDA label. In fact, during the November 2015 Meeting, Gardner recalled defendant Polymeropoulos stating that "[d]octors will ask you if Fanapt can be dosed once daily because of the long half-life and you know what the answer to that question is? It can be!"

170. According to Gardner, in the overcoming objections section of the Fanapt Sales Aid, Vanda provided the following guidance if a doctor stated that Fanapt's "dosing is not practical for schizophrenia patients," as follows: "Fanapt half-life is 18-26 hours." According to Gardner, sales representatives understood this to mean that Fanapt should be promoted as a once daily drug, notwithstanding Fanapt's FDA label.

v. Titration

171. Moreover, the FDA-approved Fanapt label states that patients starting on the drug should use titration to achieve the target dose. The official Fanapt titration pack, however, does not follow the FDA's approved titration schedule. Fanapt sales representatives in some territories completely ignored the FDA-approved titration schedule and gave providers two or three titration packs, rubber banded together, to give to their patients starting Fanapt.

172. According to Gardner and Bourgeois, Vanda senior management made no attempt to correct the off-label message regarding the titration packs even though they were fully aware of the alleged misconduct. By providing several titration packs, Vanda helped ensure that patients would titrate above the 6 mg effective mark, and therefore increase their target dose to the higher 12 mg twice daily dose. The distribution of multiple titration packs, rubber banded together, can result in patients dosing the titration packs according to the written instruction on the package, causing the patients to rapidly titrate Fanapt, thus increasing the risk for orthostatic

hypotension (a dangerous side effect) and defeating the entire purpose of the FDA warning to slowly titrate Fanapt.

vi. Copay Fraud

173. Vanda also participated in a fraudulent scheme to misuse Fanapt copay cards. According to the Qui Tam Lawsuit, during October and November 2015, there was a large spike in Fanapt prescriptions among a certain group of physicians in Detroit, which was the result of a fraudulent scheme between the physicians and local pharmacists to submit hundreds of Fanapt copay cards and prescriptions, receive reimbursement from the insurance provider, and then pocket the money because the prescriptions were never dispensed.

174. Vanda was an active participant in this scheme because, according to Gardner, Fanapt copay cards can only be provided by a Fanapt sales representative or manager. Therefore, in order for these physicians to obtain such a large quantity of copay cards, Vanda supplied the copay cards and subsequently sought to cover it up after others took notice. After Gardner brought this issue to the attention of the management team, Ramirez, Head of Sales, helped conceal the scheme and instructed Gardner not to discuss this matter ever again.

175. As Fanapt's copay cards can be used by Medicare and Medicaid, the payments for these fake prescriptions were made by the government.

176. Taken collectively, the above allegations demonstrate that the Defendants knew, or recklessly disregarded, that the Defendants caused Vanda engaged in a multifaceted off-label promotion scheme for Fanapt during the Relevant Period, including: (i) marketing Fanapt to treat psychological disorders other than schizophrenia; (ii) focusing on akathisia to distract doctors from the underlying condition that Fanapt was being used to treat; (iii) providing unrealistic sales targets that required off-label promotion in order to be met; (iv) compensating sales representatives for off-

label sales; (v) targeting pediatric patients as part of the sales efforts for Fanapt; (vi) presenting Fanapt as a first line treatment; (vii) downplaying the extent and severity of QT prolongation; and (viii) promoting that Fanapt can be administered once-daily.

177. Moreover, the Defendants' long-running off-label promotion scheme for Fanapt rendered false and misleading the repeated statements made by the Defendants during the Relevant Period regarding the Fanapt 50, how Fanapt was being promoted and sold, and other representations in Vanda's SEC filings regarding Fanapt's marketing. In speaking about Vanda's marketing and promotional efforts for Fanapt, the Defendants had a duty to speak fully and truthfully to the public and investors. Because the Defendants failed to disclose the off-label promotion scheme for Fanapt, these statements omitted material information from Vanda's investors, thereby rendering statements made by the Defendants during the Relevant Period materially false and misleading.

F. Vanda's Off-Label Promotion of Hetlioz

178. The Qui Tam Lawsuit also alleges that Vanda wrongfully promoted Hetlioz for off-label uses.

i. Hetlioz was Approved to Treat Non-24 Among the Blind

179. Hetlioz was first granted orphan drug status by the FDA on January 19, 2010, for the treatment of Non-24 in blind patients without light perception. However, after releasing the drug, Vanda quickly targeted sighted patients as their primary market for Hetlioz.

180. On May 31, 2013, Vanda submitted an NDA to the FDA "to support marketing of [Hetlioz], a melatonin agonist, for the treatment of Non-24 hour sleep-wake disorder (Non-24) in totally blind patients."

181. According to the FDA's Summary Review of the Hetlioz NDA, Non-24 occurs principally, if not totally, in blind people. Specifically, the FDA's Summary Review states, in pertinent part, that:

> Non-24 hour sleep-wake disorder is characterized by a mismatch between the timing of the sleep-wake cycle and the 24-hour day because of a lack of environmental light input *in completely blind individuals*. As the individual "biological clock" runs longer than 24 hours in most people, the absence of light input creates a cyclical misalignment of sleep and wakefulness with the 24-hour day.

182. According to the National Sleep Foundation ("NSF"), a nonprofit foundation whose largest single source of funding is pharmaceutical companies, Non-24 requires a formal diagnosis by a doctor.

183. In particular, according to the NSF, "blood, saliva, or urine should be collected [by a doctor] over several weeks to look for circadian biochemical chemical rhythms that can determine for sure whether the clock is exhibiting a non-24-hour rhythm." This is because Non-24 "has been misdiagnosed for other sleep deprivation or non-related psychiatric disorders in the past." Thus, according to the NSF, Non-24 should be tested for and observed by medical professionals before an individual is determined to have Non-24, as opposed to a different kind of sleep disorder. Non-24 rarely, if ever, occurs in sighted individuals.

184. Before the Relevant Period, the Defendants repeatedly acknowledged that Non-24 rarely, if ever, occurs in sighted individuals. For example, in an investor presentation that Vanda filed on Form 8-K on March 9, 2010, the Company described Non-24 as a disorder that "[o]ccurs almost entirely in subjects who are totally blind and lack the light sensitivity necessary to reset the circadian clock."

185. In support of the NDA for Hetlioz, Vanda conducted two clinical trials. According to the FDA label for Hetlioz, both studies involved "totally blind patients with Non-24."

186. In a January 26, 2012 press release issued by Vanda, announcing initial trial results from one of the clinical trials referenced in the FDA label for Hetlioz, Vanda stated, in pertinent part, as follows:

> Tasimelteon [Hetlioz] is a circadian regulator in development for the treatment of Non-24-Hour Disorder in totally blind individuals with no light perception.
>
> * * *
>
> Circadian regulation is necessary for the treatment of Non-24-Hour Disorder and it is predictive of a beneficial effect on both nighttime sleep and daytime naps. While light resets the body clock in sighted individuals, keeping it synchronized with the 24-hour day, this effect is lost in totally blind individuals with no light perception.

187. On November 14, 2013, Vanda issued a press release, which was subsequently filed on Form 8-K on November 15, 2013 (the "11/15/13 Form 8-K"), announcing that the FDA had voted to recommend the approval of Hetlioz "for the treatment of Non-24-Hour Disorder (Non-24) in the *totally blind*."

188. Defendant Polymeropoulos stated in the 11/15/13 Form 8-K, in pertinent part, that: "[w]e are now one step closer toward our goal of providing a treatment option that addresses the physiologic cause of this serious, debilitating orphan condition that impacts a majority of totally blind individuals."

189. The FDA officially approved Hetlioz in January 2014.

190. During the Relevant Period, the Defendants continued to acknowledge that Non-24 rarely, if ever, occurs in sighted individuals, even as the Company aggressively marketed and promoted Hetlioz off-label to sighted individuals.

191. For example, on March 7, 2017, defendant Kelly participated at the Cowen Health Care Conference and stated to Vanda's investors, in pertinent part, as follows:

> But first, some background on non-24 itself. This is a rare circadian rhythm disorder that impacts approximately 80,000 individuals in the US. *It occurs almost exclusively in the totally blind*, and these are blind individuals without light perception which, in turn, inhibits their ability to reset their circadian clock.

ii. <u>Vanda Promotes Hetlioz Off-Label to Psychiatrists Treating General Sleep Disorders</u>

192. Although Vanda repeatedly acknowledged that Non-24 rarely, if ever, occurs in sighted individuals, the Company focused its promotional efforts for Hetlioz during the Relevant Period on sighted individuals regardless of whether they had Non-24. Even worse, Vanda's promotional efforts for Hetlioz were concentrated on psychiatrists, who focus on the diagnosis and treatment of mental health disorders, not on treating blind patients and let alone patients who may be experiencing any type of sleeping disorder, least of all Non-24. Instead, the Defendants undertook a scheme to promote Hetlioz off-label.

193. According to Gardner and Bourgeois, during the November 2015 Meeting, the Fanapt 50 and the RBLs were instructed to ensure that Hetlioz was introduced to the same psychiatrists that were being targeted for Fanapt.

194. According to Gardner, to pitch Hetlioz to psychiatrists, defendant Polymeropoulos instructed the RBLs to direct the sales representatives to ask them, "do you have any blind patients?" Regardless of the answer, the sales representatives were instructed to state

that "Hetlioz is a drug that is effective in treating circadian rhythm disruption" and to leave the doctor with a Hetlioz sales packet.

195. Defendant Polymeropoulos told the RBLs that psychiatrists would understand that if Hetlioz treats circadian rhythm disruption in Non-24 that it could also treat non-blind patients with other sleep disorders caused by circadian rhythm disruption, such as shift work sleep disorder, jet lag, and insomnia.

196. According to Gardner and Bourgeois, this sales pitch was designed to, and in fact did, result in off-label prescriptions of Hetlioz.

197. According to Gardner and Bourgeois, at no point in time during either of their employments with Vanda did anyone discuss with them that Non-24 should be diagnosed by a doctor, or that blood and urine tests should be part of a Non-24 diagnosis. To the contrary, Gardner and Bourgeois recount that Vanda informed them that there was no way to tell if someone had Non-24, which is why the drug could be used to treat any circadian rhythm disorder.

198. According to Bourgeois, if physicians would inquire about whether there was any way to test patients for Non-24, Vanda trained its representatives to respond by pivoting the conversation to discussing that individuals with mental disorders were good candidates for Hetlioz because many of them have difficulty sleeping.

199. After the Fanapt 50 pitched Hetlioz to a psychiatrist, they were required to pass the account over to a Hetlioz sales representative, who would try to close the sale. Vanda referred to these as "pass-alongs." Vanda informed the Fanapt 50 that they would be held accountable for how many pass-alongs they provided to the Hetlioz sales team. According to

Gardner, the number of pass-alongs a sales representative secured was documented in these representatives' company-issued laptops following every sales call.

200. According to Gardner, in May 2016, Ramirez held a meeting with the RBLs and reprimanded them because the Fanapt 50 were not producing enough pass-alongs. During the call, some of the RBLs stated that the psychiatrists who the Fanapt 50 were contacting did not have any blind patients. Ramirez responded that it was mandatory that the Fanapt 50 promote Hetlioz on every sales call.

201. According to Bourgeois, Vanda intended to promote Hetlioz off-label for conditions other than Non-24. Bourgeois recounts that sales representatives were trained to respond to a question from doctors asking if Hetlioz is only for blind patients by stating that if a patient does not have normal sleep habits, then they should use Hetlioz regardless of whether they are blind.

202. According to Bourgeois, some doctors would ask how they could tell if their patients had Non-24. Bourgeois recounts that Vanda trained its sales representatives to respond by telling the doctor that if their patient had tried other sleep aids and were still experiencing sleep issues, that they probably have Non-24.

203. According to Bourgeois, several sales representatives expressed concerns about selling Hetlioz to sighted patients and asked Vanda's senior management to see data that supported the efficacy of Hetlioz in sighted patients. Bourgeois recounts that Vanda's senior management responded that Non-24 occurs in blind patients but also those with mental conditions, so that if a psychiatrist has patients who have trouble sleeping and have tried Ambien without success, that they should prescribe Hetlioz.

204. According to Bourgeois, Vanda's promotional materials for Hetlioz also demonstrated an intent to promote Hetlioz off-label because they did not focus on patients with Non-24. Instead, the call guidance sheets for Hetlioz instructed sales representatives to tell doctors that "Non-24 has been associated with traumatic brain injury and depressive and bipolar mood disorders. Blindness is also a risk factor."

205. In addition, according to Bourgeois, in early 2018 he was contacted by Arnold regarding his usage of the word "sleep" as opposed to "Non-24" in his sales representative reports for Hetlioz. Bourgeois recounts that Arnold told him that the word "sleep" needed to be removed from Hetlioz sales representative reports because defendant Polymeropoulos was concerned about being sued by the government. Bourgeois ultimately removed "sleep" from his Hetlioz sales representative reports.

206. According to Bourgeois, Arnold informed him that other RBLs were using the word "sleep" in their Hetlioz sales representative reports and that she had been raising the same concerns with them.

207. Further, according to Bourgeois, Hetlioz was being promoted off-label because certain sales representatives were able to obtain an out-sized number of prescriptions written for Hetlioz, while most struggled to achieve more than one or two prescriptions per fiscal quarter.

208. For example, Bourgeois recounts that Scott Grontkowski ("Grontkowski"), a Vanda sales representative from Rockford, Illinois, from January 2017 to the present, had gotten doctors to write over 50 prescriptions for Hetlioz in a quarter, even though according to Bourgeois, none of these prescriptions were for blind patients.

209. In FY17, Vanda sold almost $90 million worth of Hetlioz. At Hetlioz's price of $148,000 per year, this meant that Vanda had written approximately 608 prescriptions for

Hetlioz during FY17. Assuming he only sold 50 prescriptions, Grontkowski accounted for approximately 8.2% of the Hetlioz prescriptions written in FY17.

210. According to Bourgeois, Grontkowski was asked by Vanda to present at the Company's 2018 national sales meeting (the "2018 Meeting") to demonstrate his pitch for selling Hetlioz. Griffin, Ramirez, and defendant Reverberi attended the 2018 Meeting, which took place in Washington, D.C.

211. Bourgeois recounts that Grontkowski's sales pitch during the 2018 Meeting contained nothing about Hetlioz's efficacy in treating Non-24. Instead, Bourgeois recounts that Grontkowski stated during the 2018 Meeting that Grontkowski tells doctors if they have patients who cannot sleep, they should prescribe them Hetlioz to get them sleeping right now.

iii. The "Hetlioz to Psychiatrists Initiative"

212. During the early part of the Relevant Period, the Defendants did not acknowledge that its Fanapt sales force was being used to promote Hetlioz to psychiatrists.

213. That changed in July 2017, when Vanda announced it was beginning the "Hetlioz to Psychiatrists Initiative," which the Defendants termed "HPI." According to the Defendants, the HPI involved having Fanapt sales representatives call psychiatrists to promote Hetlioz.

214. According to Gardner and Bourgeois, however, even though the HPI was announced as beginning in July 2017, Vanda had been using Fanapt sales representatives to promote Hetlioz since at least November 2015.

215. On February 11, 2019, the Aurelius Report publicly revealed for the first time, among other things, the Defendants' off-label marketing scheme for both Fanapt and Hetlioz. As stated in the Aurelius Report, according to a former unnamed Vanda sales representative,

"[w]e were [internally] saying 'give it to everyone who doesn't sleep well.'" A sleep doctor stated in the Aurelius Report that "[Vanda is] prescribing [Hetlioz] off label and calling it's [sic] something it's not."

G. Tradipitant

216. Of the few drugs that Vanda had in clinical development during the Relevant Period, tradipitant was the most promising in terms of potentially obtaining FDA approval. According to defendant Polymeropoulos during a conference call held on November 7, 2017 for analysts and investors to discuss Vanda's financial results and performance for 3Q17, "[t]radipitant [is] the most exciting clinical milestone for Vanda[.]"

217. For this reason, investors and analysts placed importance on tradipitant's prospects during the Relevant Period.

218. Tradipitant was being clinically tested by Vanda during the Relevant Period for two potential indications: (i) gastroparesis, a disorder that prevents the stomach from emptying food in a normal fashion; and (ii) atopic dermatitis (eczema).

219. According to defendant Polymeropoulos, tradipitant's potential for treating gastroparesis presented a significant economic opportunity for Vanda. During a conference call with analysts and investors held on December 3, 2018, defendant Polymeropoulos stated, in pertinent part, that:

> Before going into more detail on the study results, I would like to provide an overview of the significant unmet medical need for gastroparesis patients.
>
> Gastroparesis is a serious chronic medical condition, characterized by delayed gastric emptying and associated with the symptoms of nausea, vomiting, bloating, fullness after meals, abdominal pain, along with significant impairment of social and occupational functioning.

> The estimated prevalence of gastroparesis in the U.S. is over 5 million people, many of whom remain undiagnosed.
>
> Gastroparesis affects mostly women, and it can be of various etiologies including diabetes mellitus and idiopathic causes.
>
> The only U.S. Food and Drug Administration approved treatment for gastroparesis is metoclopramide, approved in 1979, which due to its potential of severe side effects, carries a black box warning and has limitations of use of no more than 3 months.
>
> Patients are faced with limited therapeutic options and clinical guidelines recommend in addition to metoclopramide, the off-label use of different drugs including erythromycin, domperidone, which is not approved in the U.S., botulinum toxin injections, gastric simulators and a variety of surgical procedures in an effort to relieve, even temporarily, some of the symptoms of the disease.
>
> Gastroparesis treatment represents a significant unmet medical need as underscored by the testimonies of interested parties and advocacy organizations included the International Foundation for Gastrointestinal Disorders and Gastroparesis Patient Association for Cures and Treatments.

220. Tradipitant's potential for treating gastroparesis was a central focus of Vanda's clinical trial efforts for tradipitant during the Relevant Period.

221. Given the importance of tradipitant to Vanda's clinical pipeline, the Company spent the bulk of its direct project costs for its clinical trial drugs on tradipitant.

222. According to the Form 10-K for FY17 (the "2017 Form 10-K"), Vanda spent $11.645 million on direct project costs for tradipitant during FY17 out of $15.997 million spent on direct project costs for its clinical trial drugs, or 72.7%.

223. According to the Form 10-Q for 1Q18 ("1Q18 Form 10-Q"), Vanda spent $2.277 million on direct project costs for tradipitant during 1Q18 out of $3.619 million spent on direct project costs for its clinical trial drugs, or 62.9%.

224. According to the Form 10-Q for 2Q18 ("2Q18 Form 10-Q"), Vanda spent $4.372 million on direct project costs for tradipitant during 2Q18 out of $5.974 million spent on direct project costs for its clinical trial drugs, or 73.2%.

225. According to the Form 10-Q for 3Q18 ("3Q18 Form 10-Q"), Vanda spent $5.113 million on direct project costs for tradipitant during 3Q18 out of $7.142 million spent on direct project costs for its clinical trial drugs, or 71.6%.

226. Accordingly, during the Relevant Period, Vanda's clinical trial efforts for tradipitant were of high importance such that knowledge of the efforts can reasonably be attributed to management and the Board.

i. Vanda Admits in the FDA Litigation that it Knew a Clinical Trial Hold Would be Placed on Critical Tradipitant Studies

227. On May 29, 2019, Vanda filed an amended complaint in the FDA Litigation (the "Vanda FDA Complaint"), which contained Vanda's allegations against the FDA regarding a clinical trial hold that has been placed on certain tradipitant studies that were highly material and important to Vanda's investors. On July 10, 2019, Vanda filed a memorandum of law in support of its motion for summary judgment in the FDA Litigation (the "Vanda MSJ Brief"). The Vanda MSJ Brief contains citations to documents included in the Index of Administrative Records prepared by the FDA for the FDA Litigation.

228. According to the Vanda FDA Complaint, Vanda submitted its original protocol for VLY686-2301 ("Study 2301") to the FDA on August 17, 2016. Study 2301 was "a multicenter, randomized, double-blind placebo-controlled study of tradipitant for subjects diagnosed with gastroparesis."

229. According to the Vanda FDA Complaint, Study 2301 was initiated on November 22, 2016.

230. Study 2301 was a Phase II trial. According to the FDA, clinical trials are often conducted in three phases, with Phase III trials generally involving more patients and a longer duration than Phase II trials. This means that even if Study 2301 were successful, Vanda still needed to conduct a Phase III trial on gastroparesis for the FDA to approve tradipitant to treat gastroparesis.

231. According to the Vanda FDA Complaint, Vanda subsequently submitted several protocol amendments to the FDA with respect to the duration of Study 2301.

232. According to the Vanda FDA Complaint, on December 5, 2017, Vanda submitted protocol amendment #5, which, among other things, provided for Study 2301 to last for eight weeks, consisting of a four-week screening phase followed by a four-week evaluation phase.

233. According to the Vanda FDA Complaint, on April 10, 2018, Vanda submitted protocol amendment #6 to, among other things, extend Study 2301 to add a 52-week, open-label extension period. Effectively, protocol amendment #6 sought to greatly expand the duration of Study 2301.

234. According to the Vanda FDA Complaint, during a May 15, 2018, teleconference between the FDA and Vanda (the "5/15/18 Call"), the FDA informed Vanda that the Company could not extend Study 2301 to be a full year clinical trial unless Vanda first completed a 9-month non-rodent toxicity study on tradipitant.

235. The FDA requires toxicity studies for drugs like tradipitant to ensure that they are safe for use in humans. Thus, it was not surprising that the FDA would want tradipitant to be tested in animals for nine months before being used on humans in a one-year study.

236. According to the FDA, one of their roles during the clinical trial process is to protect volunteers who participate in such trials from unreasonable and significant risk. For this

reason, the FDA has the power to place a clinical hold on a trial that exposes its participants to such risk.

237. According to the FDA, "[a] clinical hold is rare; instead, FDA often provides comments intended to improve the quality of a clinical trial." This is consistent with the FDA's mandate to allow "wide latitude in clinical trial design."

238. According to the Vanda MSJ Brief, at all relevant times, the FDA "made clear that continued human trials beyond 3 months [for tradipitant] would not be allowed to proceed without a 9-month [toxicity] study[.]"

239. According to the Vanda FDA Complaint, during the 5/15/18 Call, the FDA informed Vanda that, if the nine-month non-rodent study was not conducted, the FDA would place a clinical hold on Study 2301 to prevent the 52-week extension study.

240. According to the Vanda MSJ Brief, the FDA stated during the 5/15/18 Call that "chronic toxicology studies in 2 species is a requirement, not a recommendation, prior to proceeding to long-term studies in humans."

241. Thus, as of the 5/15/18 Call, the Defendants surely knew that, if they chose not to conduct the nine-month non-rodent study, a fully year clinical trial for tradipitant would not be approved by the FDA.

242. According to the Vanda MSJ Brief, on May 18, 2018, the FDA concluded that "a chronic toxicology study of 9 months duration will be needed" and that tradipitant "trials beyond 3 months 'should be put on clinical hold until the chronic toxicity study in a non-rodent species is submitted for our review.'"

243. According to the Vanda FDA Complaint, to avoid a clinical hold being placed on Study 2301, Vanda submitted an amended protocol to the FDA on May 22, 2018, that, among other things, limited Study 2301 to no more than three months in duration.

244. According to the Vanda FDA Complaint, on May 24, 2018, the FDA approved the amended protocol and allowed Study 2301 to proceed for no longer than three months in duration without having to first conduct the nine-month non-rodent toxicity study.

245. According to the Vanda MSJ Brief, on August 1, 2018, Vanda filed a formal dispute resolution request contesting the FDA's determination that the nine-month non-rodent toxicity study was necessary in order to conduct a clinical trial for gastroparesis in excess of three months. According to the Vanda MSJ Brief, the FDA responded to this request by sending Vanda a one-page letter stating that Vanda's formal dispute "was 'not accepted.'"

246. According to the Vanda FDA Complaint, on September 26, 2018, Vanda submitted a new clinical study protocol, Study 2302, to the FDA that was the same 52-week open-label extension study that Vanda proposed as protocol amendment #6 for Study 2301.

247. According to the Vanda FDA Complaint, as of November 2018, Vanda had not begun Study 2302. On December 3, 2018, the Company issued a press release, which was also filed on Form 8-K, which announced positive results from Study 2301 (the "12/3/18 Form 8-K"). According to the 12/3/18 Form 8-K and the conference call the Company held that same day to report the results from Study 2301, this Phase II study was successful but an additional, longer study that also had positive results was ultimately needed in order to obtain FDA approval for tradipitant to treat gastroparesis.

248. According to the Vanda FDA Complaint, on December 11, 2018, Vanda submitted a protocol amendment to Study 2301 that once again requested to add a 12-month

open-label extension to Study 2301. According to the Vanda FDA Complaint, this proposed amendment to Study 2301 is similar to Study 2302.

249. According to the Vanda FDA Complaint, on December 19, 2018, the FDA informed Vanda by telephone that both Study 2301 and Study 2302 had been placed on partial clinical holds because Vanda had not complied with the FDA's request – communicated to Vanda on the 5/15/18 Call — that the Company conduct a nine-month non-rodent toxicity to study to ensure that tradipitant is safe for long-term use in humans.

250. According to the Vanda FDA Complaint, on December 21, 2018, the FDA provided Vanda with a letter that contained a written explanation for the partial clinical trial holds placed on Study 2301 and Study 2302. According to the Vanda FDA Complaint, the FDA reiterated in its December 21, 2018 letter, in pertinent part, that "non-rodent toxicity studies of 9 months duration are required for the conduct of [Vanda's] proposed clinical investigations of 52 weeks (12 months) duration[.]"

251. According to the initial complaint filed by Vanda in the FDA Litigation on February 5, 2019, the FDA could not have been more clear that, at all relevant times in 2018, Vanda's failure to conduct the nine-month non-rodent toxicity study would result in a clinical hold, with Vanda alleging, in pertinent part, that:

> Throughout 2018, including in the Clinical Hold Letter and in Vanda's conversations with [the FDA], FDA made clear that, one way or another, Vanda would be obligated to conduct the nine-month study[.]

252. According to the Vanda FDA Complaint, on December 21, 2018, Vanda requested a reconsideration of the partial clinical holds imposed by the FDA.

253. According to the Vanda FDA Complaint, on January 4, 2019, the FDA informed Vanda it was denying the Company's request for reconsideration.

254. The Defendants did not tell investors about the threat to Vanda's clinical testing regime for tradipitant caused by the Company's refusal to conduct a routine safety test on tradipitant until after the market closed on February 5, 2019, when, to the surprise of investors and analysts, Vanda issued a press release announcing that it had initiated the FDA Litigation to, among other things, lift the partial clinical holds. On this news, the trading price of Vanda's common stock declined by $5.00 per share, or 19.95%.

255. Analysts were deeply concerned by the Defendants' decision to sue the FDA, and the Company's related refusal to conduct a routine safety test for tradipitant. For example, in a February 6, 2019 report on Vanda, analyst Ester Rajavelu of Oppenheimer & Co. stated:

> VNDA's announcement that it is pursuing legal action against the FDA due to a partial clinical hold restricting tradipitant dosing to 3 months **comes as a surprise to us**. The FDA is requesting tox data from a nine month non-rodent study to allow longterm dosing in clinical trials. While management acknowledges this would be a low cost study it believes FDA's requirement to be unethical due to the euthanizing of dogs (we note other non-human mammals could also be used). While our valuation does not include tradipitant revenues, we view a lawsuit as a non-optimal strategy….
>
> * * *
>
> We note the FDA's request for nine-month tox data from non-human mammals is not unusual given gastroparesis and atopic dermatitis are chronic conditions requiring long-term therapy.

256. In addition, in a February 6, 2019 report on Vanda, analyst Derek Archila of Stifel Nicolaus stated:

> We believe VNDA's decision to sue the FDA for what it feels are unnecessary animal studies' and due to the company's current refusal to run these studies having resulted in a partial clinical hold on tradipitant, *this will certainly raise questions among investors about the clinical timelines for this program and whether or not management is really focused on creating value for its shareholders*.

257. Likewise, a February 12, 2019 *Washington Business Journal* report on Vanda, which includes quotes from an interview conducted by the *Washington Business Journal* with defendant Polymeropoulos that day, stated:

> While the clinical hold doesn't affect Vanda's timing for filing an application for FDA approval at this point, it could delay progress if it's not resolved in the next few months, Polymeropoulos said. That's because the hold isn't on ongoing studies - Vanda plans to start a new phase 3 study in gastroparesis in the next few months. But it would postpone proposed studies to treat patients for longer than three months, a typical requirement for market authorization. "So if we were not allowed to collect this information at the time of filing, we're not going to have sufficient information to seek approval," Polymeropoulos said.

258. Vanda's refusal to conduct the necessary safety testing for tradipitant during the Relevant Period rendered false and misleading the repeated statements made by the Defendants during the Relevant Period regarding the progress of Study 2301, tradipitant's future prospects given the positive results of Study 2301, and other representations in Vanda's SEC filings regarding tradipitant. The Defendants were informed during the 5/15/18 Call that the FDA would not approve an extended study of tradipitant if Vanda did not conduct the required safety testing, yet the Defendants knowingly failed to include this information when communicating to Company investors, thereby rendering the statements made materially false and misleading.

H. Defendants Caused Vanda to Issue False and Misleading Statements in Breach of Their Fiduciary Duties

259. Defendants caused Vanda to issue materially false and/or misleading statements, as well as omit disclosure of material adverse facts about the Company's business, operations, and prospects. Specifically, the Company failed to disclose to investors that: (i) Vanda was engaged in a fraudulent scheme in which the Company promoted Fanapt and Hetlioz for off-label uses; (ii) Vanda was fraudulently receiving drug reimbursements from the government by abusing Medicare, Medicaid, and Tricare programs; (iii) as a result of the scheme, Vanda faced

the Qui Tam Lawsuit; (iv) Vanda's promotional materials for Fanapt and Hetlioz were false and misleading, garnering regulatory scrutiny from the FDA; (v) Vanda's decision to forgo a routine safety study that the Company knew would result in a clinical trial hold for tradipitant; and (vi) as a result, the statements about Vanda's business, operations and prospects were materially false and misleading and/or lacked a reasonable basis at all relevant times.

260. The Relevant Period begins on November 4, 2015. The previous day, on November 3, 2015, Vanda held a conference call after the market closed to discuss earnings for the third quarter of 2015. During the conference call, Defendant Polymeropoulos discussed the sales and marketing for Fanapt, stating in relevant part:

> We are seeking to stabilize the Fanapt revenue with active commercial efforts. Specifically, in early August, we launched a 12-person team in parallel territories around the United States. Early analysis of the data suggests that in these 12 territories, Fanapt revenue is beginning to stabilize. We're now in the process of further building out a small Fanapt dedicated sales force for a total of 50 territories around the country by the end of this year.
>
> * * *
>
> In July/August we launched our pilot, the Fanapt 12 looking at creating a competitive share of voice in certain territories to determine the promotional responsiveness of Fanapt when we had a competitive share of voice. And when we drilled down at the individual territory level, we were able to measure the promotional response based up on reach and frequency. And based upon the early data, it provided a strong signal confirming the promotional sensitivity of Fanapt.
>
> Based upon those data, we have decided to expand the Fanapt 12 to Fanapt 50, where we are going to be populating 50 of the most productive territories, creating a competitive share of voice, which we think we will be able to replicate the results that we saw within the Fanapt 12 and stabilize the Fanapt business exiting 2015.
>
> * * *
>
> Fanapt comes in several doses -- 1 milligram, 2, 4, 6, 8, 10, 12 and a titration pack. Based on the demand and understanding how the product is

> used, we took a price increase on the 6 and 8 milligrams, which was a significant jump of about 30% or so. The 12 milligrams was adjusted in what appears to be 100% but actually it is consistent with the use of 12 milligrams as once a day, and therefore it was adjustment for usage. Now, the net Fanapt increase overall is actually small. It is about a 15% net, taking into account that 40% of the patients are on Medicaid, and price increases based on the legislation result in additional rebates leading to actually a decrease, a net decrease of the Medicaid channel.

261. During the call, Gibbs stated the following:

> And when we drilled down at the individual territory level we were able to measure the promotional response based upon reach and frequency and based upon the early data it provided a strong signal confirming the promotional sensitivity of Fanapt. Based upon those data, we have decided to expand the Fanapt 12 to Fanapt 50 where we're going to be populating 50 of the most productive territories creating a competitive share of voice which we think we will be able to replicate the results that we saw within the Fanapt 12 and stabilize the Fanapt business exiting 2015.

262. The statements and omissions set forth above were false and misleading because Fanapt revenue, the abovementioned "competitive share of voice" and "promotional sensitivity" were driven, largely by improper, misleading and fraudulent sales practices, which include: (i) promoting Fanapt for uses outside of treating schizophrenia, the drug's sole indication; (ii) promoting Fanapt off-label to pediatric patients; (iii) overstating Fanapt's efficacy to providers; (iv) downplaying the safety risks associated with Fanapt; (v) misleading providers about Fanapt's approved dosing schedule; (vi) improperly providing titration packets in violation of the FDA-approved titration schedule and without adequate instructions for use; and (vii) promoting Fanapt as a first line therapy.

263. On November 4, 2015, Vanda filed a Form 10-Q for 3Q15 (the "3Q15 Form 10-Q"), which was signed by defendants Polymeropoulos and Kelly. The 3Q15 Form 10-Q detailed the importance to Vanda of successfully commercializing Fanapt, sating: "Our ability to generate

meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt®."

264. By speaking about the topic of the importance of successfully commercializing Fanapt, the Defendants had a duty to speak fully and truthfully. Because the Defendants failed to disclose that Vanda was using an off-label promotion scheme to commercialize Fanapt, this statement omitted material information from Vanda's investors, thereby rendering this statement materially false and misleading. Defendants' failure to adequately disclose an accurate portrayal of the Company's efforts to market and sell Fanapt during the Relevant Period further rendered this statement materially false and misleading.

265. On November 19, 2015, defendant Polymeropoulos participated at the Jefferies Autumn Global Healthcare Conference (the "11/19/15 Conference") to discuss the Company and its business. During the 11/19/15 Conference, defendant Polymeropoulos stated:

> Some of the side effects are — include metabolic weight, movement disorders, but there is one that Fanapt/iloperidone can differentiate itself, and that is akathisia. Akathisia is a state of inner restlessness often leading to suicidal thoughts and many times completed suicide. And that is not a symptom of schizophrenia. It is a side effect of the drugs to treat schizophrenia. Unfortunately, many of these new drugs that are offered quite a bit to patients have a mechanism of action that develops the side effect of akathisia. Fanapt does not have it. And on the US label, you can read that the akathisia rates for Fanapt are equal to placebo. So we believe there is a place for Fanapt in the schizophrenia market and the opportunity can be significant.
>
> * * *
>
> We have not put commercial effort behind [Fanapt] yet. Some effort began as a pilot of 12 account managers in August. And now with encouraging results in the pilot, we are moving to building a 50-person sales force in the US.

266. By speaking about the topic of Fanapt's relatively low rate of akathisia in the context of treating schizophrenia, the Defendants had a duty to speak fully and truthfully.

Because the Defendants failed to disclose that Vanda was using Fanapt's potential in reducing akathisia as a central part of its off-label promotion scheme for Fanapt, this statement omitted material information from Vanda's investors, thereby rendering this statement materially false and misleading. The Defendants' failure to adequately disclose an accurate portrayal of the Company's efforts to market and sell Fanapt during the Relevant Period further rendered this statement materially false and misleading.

267. On February 10, 2016, the Company held a conference call for analysts and investors (the "2/10/16 Call") to discuss Vanda's financial results and performance for the fourth fiscal quarter of 2015 ("4Q15") and FY15. During the 2/10/16 Call, defendant Polymeropoulos stated:

> In late Q4, we completed the launch of a 50-person Fanapt-dedicated sales force, which is promoting Fanapt primarily to psychiatrists across the U.S. Our goal is to stabilize the unit demand for Fanapt with this effort.

This statement was materially false and misleading for the reasons set forth in, *inter alia*, ¶¶106-147 and 183-206.

268. On February 12, 2016, Vanda filed its annual report for the year ended December 31, 2015 with the SEC on Form 10-K ("2015 Form 10-K"). The 2015 Form 10-K was signed by Defendants Polymeropoulos, Kelly, Watkins, Bate, Cola, Dugan, Milano and Pien. It was also accompanied by signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by Defendants Polymeropoulos and Kelly. Both Polymeropoulos and Kelly certified that the form "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report." They also certified that "the financial statements, and other financial information included in this

report, fairly present in all material respects the financial condition, results of operations and cash flows of the [Company] as of, and for, the periods presented in this report."

269. The 2015 Form 10-K discusses the importance to Vanda of successfully commercializing Fanapt, and stated: "Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt®." These statements were false and misleading for the reasons set forth in, *inter alia*, ¶¶106-168.

270. The 2015 Form 10-K discussed the uses and marketing of Fanapt and Hetlioz, stating in relevant part:

> HETLIOZ®
>
> Commercial opportunity: Non-24
>
> In January 2014, HETLIOZ® was approved in the U.S. for the treatment of Non-24. Non-24 is a serious, rare and chronic circadian rhythm disorder characterized by the inability to entrain (synchronize) the master body clock with the 24-hour day-night cycle. HETLIOZ® is the first FDA approved treatment for Non-24. HETLIOZ® is a melatonin agonist of the human MT1 and MT2 receptors, with greater specificity for MT2. These receptors are thought to be involved in the control of circadian rhythms. HETLIOZ® is believed to reset the master body clock in the suprachiasmatic nucleus (SCN), located in the hypothalamus, resulting in the entrainment and alignment of the body's melatonin and cortisol rhythms to the 24 hour day-night cycle. HETLIOZ® was launched commercially in the U.S. in April 2014. In addition, in July 2015, the EC granted centralized marketing authorization with unified labeling for HETLIOZ® for the treatment of Non-24 in totally blind adults. This authorization is valid in the 28 countries that are members of the European Union, as well as European Economic Area members Iceland, Liechtenstein and Norway.
>
> In January 2010, the FDA granted orphan drug designation status for HETLIOZ® in Non-24 in blind individuals. The FDA grants orphan drug designation to drugs that may provide significant therapeutic advantage over existing treatments and target conditions affecting 200,000 or fewer U.S. patients per year. Orphan drug designation provides potential financial and regulatory incentives, including study design assistance, tax credits, waiver of FDA user fees, and up to seven years of market exclusivity upon marketing approval. In February 2011, the European

Medicines Agency (EMA) designated HETLIOZ® as an orphan medicinal product for the same indication.

Non-24 is a serious, rare and chronic circadian rhythm disorder characterized by the inability to synchronize the master body clock with the 24-hour day-night cycle. Non-24 affects a majority of totally blind individuals, or between 65,000 and 95,000 people in the U.S. Non-24 occurs almost entirely in individuals who lack the light sensitivity necessary to synchronize the master body clock in the brain with the 24-hour day-night cycle. Most people have a master body clock that naturally runs longer than 24-hours and light is the primary environmental cue that resets it to 24 hours each day. Individuals with Non-24 have a master body clock that is not reset, and continually delays, resulting in prolonged periods of misalignment between their circadian rhythms and the 24-hour day-night cycle, including the timing of melatonin and cortisol secretion. As a result of this misalignment, Non-24 is associated with significant disruption of the sleep-wake cycle and impairments in social and occupational functioning, and marked subjective distress**.** Individuals with Non-24 cycle in-and out-of phase and suffer from disrupted nighttime sleep patterns and/or excessive daytime sleepiness.

While there are no FDA or EC approved treatments for Non-24, other than HETLIOZ®, there are a number of drugs approved and prescribed for patients with sleep disorders. The most commonly prescribed drugs are hypnotics.

* * *

Fanapt®

Commercial Opportunity: Schizophrenia

Fanapt® is a product for the treatment of schizophrenia. In May 2009, the FDA granted U.S. marketing approval of Fanapt® for the acute treatment of schizophrenia in adults. In October 2009, we entered into an amended and restated sublicense agreement with Novartis. We had originally entered into a sublicense agreement with Novartis in June 2004 pursuant to which we obtained certain worldwide exclusive licenses from Novartis relating to Fanapt®. Pursuant to the amended and restated sublicense agreement, Novartis had exclusive commercialization rights to all formulations of Fanapt® in the U.S. and Canada. In January 2010, Novartis launched Fanapt® in the U.S. On December 31, 2014, Novartis transferred all the U.S. and Canadian commercial rights to the Fanapt® franchise to Vanda as part of the Settlement Agreement. See Note 3, Settlement Agreement with Novartis, to the consolidated financial statements included in Part II of this annual report on Form 10-K for

additional information. In June 2015, we announced positive results from REPRIEVE, a Phase III long-term maintenance study that was conducted by Novartis. In September 2015, the FDA accepted for review a supplemental New Drug Application (sNDA) for Fanapt® for the maintenance treatment of schizophrenia in adults. The FDA has set a May 2016 PDUFA date for the Fanapt® sNDA.

271. The 2015 Form 10-K also discussed reimbursement from government programs, stating in relevant part:

Third-party reimbursement and pricing controls

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, collectively referred to as the ACA, has changed and is expected to further significantly change the way healthcare is financed by both governmental and private insurers. The provisions of the ACA became effective over various periods from 2010 through 2014. We cannot predict the complete impact of the ACA on pharmaceutical companies because many of the ACA's reforms require the promulgation of detailed regulations to implement the statutory provisions, which has not yet occurred. While we cannot predict the complete impact on federal reimbursement policies this law will have in general or specifically on any product we commercialize, the ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of new products. The rebates, discounts, taxes and other costs resulting from the ACA may have a significant effect on our profitability in the future. In addition, potential reductions of the per capita rate of growth in Medicare spending under the ACA, could potentially limit access to certain treatments or mandate price controls for our products. Moreover, although the United States Supreme Court has upheld the constitutionality of most of the ACA, some states have indicated that they intend not to implement certain sections of the ACA, and some members of the U.S. Congress are still working to repeal the ACA. We cannot predict whether these challenges will continue or other proposals will be made or adopted, or what impact these efforts may have on us or our partners.

In the U.S. and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payors, such as government and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us or our partners to go through the process of seeking reimbursement from Medicare and private payors. Our products may not be considered cost-effective, and coverage and reimbursement may not be available or

> sufficient to allow us or our partners to sell our compounds on a competitive and profitable basis. The passage of the Medicare Prescription Drug and Modernization Act of 2003 imposes additional requirements for the distribution and pricing of prescription drugs which may affect the marketing of our products.

The statements in the previous two paragraphs were false and misleading for the reasons set forth in, *inter alia*, ¶¶106-125 and 169-206.

272. The 2015 Form 10-K also discussed the possibility that Vanda could fail to comply with applicable laws and regulations regarding selling and promoting Fanapt, stating: "Failure to comply with government regulations regarding the sale and marketing of our products could harm our business." This statement was materially false and misleading because it failed to disclose that it was not merely possible that failing to comply with applicable laws and regulations regarding selling and marketing Fanapt could disrupt the Company's business and financial performance; this risk had already materialized because Vanda was actively and knowingly engaged in an off-label promotion scheme for Fanapt.

273. On May 4, 2016, the Company held a conference call for analysts and investors (the "5/4/16 Call") to discuss Vanda's financial results and performance for the first fiscal quarter of 2016 ("1Q16"). During the 5/4/16 Call, defendant Polymeropoulos stated:

> In the 50 territories in which we began promoting Fanapt through our sales force, we observed a significantly lower rate of demand decline as compared to non-promoted territories. As a reminder, we increased our field force from a 12-person pilot to a 50-person team in December of 2015.

These statements were false and misleading for the reasons set forth in, *inter alia*, ¶¶106-168.

274. On May 5, 2016, Vanda filed a Form 10-Q for 1Q16 (the "1Q16 Form 10-Q"), which was signed by defendants Polymeropoulos and Kelly. The 1Q16 Form 10-Q discusses the

importance to Vanda of successfully commercializing Fanapt, and stated: "Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize… Fanapt®". These statements were false and misleading for the reasons set forth in, *inter alia*, ¶¶106-168.

275. The 1Q16 Form 10-Q provided no update to the Company's risk factors since the filing of the 2015 Form 10-K, and stated:

> There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2015.

276. These statements were false and misleading because, as set forth in, *inter alia*, ¶¶106-168, the risk described in the 2015 Form 10-K regarding the potential harm to Vanda from failing to comply with applicable laws and regulations in selling and marketing Fanapt was not merely prospective; it had already materialized because Vanda was actively and knowingly engaged in an off-label promotion scheme for Fanapt.

277. On June 9, 2016, defendant Polymeropoulos participated in the 6/9/16 Conference to discuss the Company and its business. During the 6/9/16 Conference, defendant Polymeropoulos stated:

> And for those individuals who develop this restlessness [akathisia] when taking other antipsychotics, we are recommending Fanapt as a second-line treatment. As many people know, there are quite a few antipsychotics on the market and it is incredibly important to best position your drug. This is a promotionally sensitive class and so, with that said, we initiated our promotion in April of last year initially with a pilot of about 12 reps to understand the messaging, the promotional sensitivity. We expanded that field force from 12 to 50 at the end of last year, and you can see the results that we have had since bringing Fanapt back in house.

278. The statement referenced in the previous paragraph that "we are recommending Fanapt as a second-line treatment [for akathisia]" was materially false and misleading because by

speaking about the topic of Fanapt's status as a second line treatment, the Defendants had a duty to speak fully and truthfully. Because the Defendants failed to disclose that Vanda was promoting and marketing Fanapt as a first line treatment, meaning off-label, this statement omitted material information from Vanda's investors, thereby rendering this statement materially false and misleading. The Defendants' failure to adequately disclose an accurate portrayal of the Company's efforts to market and sell Fanapt during the Relevant Period further rendered this statement materially false and misleading.

279. The statement referenced in the paragraph before last that "[w]e expanded that field force from 12 to 50 at the end of last year" was materially false and misleading for the reasons set forth in, *inter alia*, ¶¶106-168.

280. On June 21, 2016, defendant Polymeropoulos participated in the JMP Securities Life Sciences Conference (the "6/21/16 Conference") to discuss the Company and its business. During the 6/21/16 Conference, defendant Polymeropoulos stated:

> We put 12 sales reps in the field last August, supplemented by another 38 in December. So now the full 50 have been on board for the first and now second quarter. So, what we see is what you described, Jason: the beginnings of stabilizing that decline. Still, we see some overall decline around the country. We did an analysis in the first quarter, where the territory supported by 50 reps are significantly outperforming white space. So, we know they are doing something good. We certainly wanted to be supported and do more, stabilize the decline and eventually return to growth.
>
> * * *
>
> We are working on differentiation with our sales force. We know from the US label that the rate of akathisia, a very significant side effect by some antipsychotics, is similar to placebo. And physicians now very quickly are becoming aware of that as well.

281. The statement referenced in the previous paragraph that "[w]e put 12 sales reps in the field last August, supplemented by another 38 in December" was materially false and misleading for the reasons set forth in, *inter alia*, ¶¶106-168.

282. The statements referenced in the paragraph before last that "[w]e are working on differentiation with our sales force" and "physicians now very quickly are becoming aware of that as well" were materially false and misleading for the reasons set forth in, *inter alia*, ¶¶105-167.

283. On July 27, 2016, the Company held a conference call for analysts and investors (the "7/27/16 Call") to discuss Vanda's financial results and performance for the second fiscal quarter of 2016 ("2Q16"). During the 7/27/16 Call, defendant Polymeropoulos stated:

> And just to address, now, specifically your question, we're very excited about the early signs of effectiveness of our 50-people sales force, in that, in the territories of the 50, we see based on IMS and Symphony Health a decline of less than 1% in the promoted territories. And that compares with a continuous decline in the white space. And just to give you an order of magnitude, our 50 territories attempt to address about 70% of the prescribing universe. So, the white space is 30%. And with that, the lesson learned is that promotion does work, and it is received well. Our sales force is doing a great job. We'll continue to try to improve our message and the effectiveness of the sales force.

284. The statements referenced in the previous paragraph that "we're very excited about the early signs of effectiveness of our 50-people sales force," "our sales force is doing a great job," and "[w]e'll continue to try to improve our message and the effectiveness of the sales force" were materially false and misleading for the reasons set forth in, *inter alia*, ¶¶106-168.

285. On July 28, 2016, Vanda filed a Form 10-Q for 2Q16 (the "2Q16 Form 10-Q"), which was signed by defendants Polymeropoulos and Kelly. The 2Q16 Form 10-Q discusses the importance to Vanda of successfully commercializing Fanapt, and stated: "Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to

successfully commercialize … Fanapt®" This statement was materially false and misleading for the reasons set forth in, *inter alia*, ¶106-168.

286. The 2Q16 Form 10-Q provided no update to the Company's risk factors since the filing of the 2015 Form 10-K, and stated, "[t]here have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2015." This statement was materially false and misleading for the reasons set forth in, *inter alia*, ¶¶106-168.

287. On November 2, 2016, the Company held a conference call for analysts and investors (the "11/2/16 Call") to discuss Vanda's financial results and performance for the third fiscal quarter of 2016 ("3Q16"). During the 11/2/16 Call, in response to an analyst's question about how the clinical profile of Fanapt fits into other possible indications for Fanapt being pursued by the Company, defendant Polymeropoulos stated:

> Just before I answer this question, just to remind everybody that Fanapt is approved for the indication of schizophrenia in adults in the US. I refer everybody for a full discussion of efficacy and safety to www.fanapt.com.
>
> * * *
>
> So we believe that Fanapt, in patients with schizophrenia, will be a drug that will be used once patients switch from another medication, primarily because of tolerability; and specifically, that specific schizophrenia patient that needs to switch and has experienced drug-induced akathisia on another drug may be actually a very well-suited patient for Fanapt.
>
> * * *
>
> We, of course, are always interested in pediatric applications. We know that two other agents in the antipsychotic space have been developed for certain symptoms of irritability in children with autism, and that is an indication part of the long-term planning for a pediatric indication.

288. The statement referenced in the previous paragraph that "Fanapt, in patients with schizophrenia, will be a drug that will be used once patients switch from another medication" was materially false and misleading for the reasons set forth in, *inter alia*, ¶¶106-168.

289. The statements referenced in the paragraph before last that "[w]e, of course, are always interested in pediatric applications [for Fanapt]," was materially false and misleading for the reasons set forth in, *inter alia*, ¶¶106-168.

290. On November 3, 2016, Vanda filed a Form 10-Q for 3Q16 (the "3Q16 Form 10-Q"), which was signed by defendants Polymeropoulos and Kelly. The 3Q16 Form 10-Q discusses the importance to Vanda of successfully commercializing Fanapt, and stated: "Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt®." This statement was materially false and misleading for the reasons set forth in, *inter alia*, ¶¶106-168.

291. The 3Q16 Form 10-Q provided no update to the Company's risk factors since the filing of the 2015 Form 10-K, and stated: [t]here have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2015. This statement was materially false and misleading for the reasons set forth in, *inter alia*, ¶¶106-168.

292. On February 15, 2017, the Company held a conference call for analysts and investors (the "2/15/17 Call") to discuss Vanda's financial results and performance for the fourth quarter of 2016 and FY16. During the 2/15/17 Call, defendant Polymeropoulos stated:

> So as we had previously communicated, the plan for this quarter is to expand the sales force from around 50 sales reps last year to about 120, increasing, therefore, both reach and ability of call frequency. And we believe that the new sales force will be trained and ready to detail physicians by the end of this quarter.

293. The statement referenced in the previous paragraph that "the plan for this quarter is to expand the sales force from around 50 sales reps last year to about 120, increasing, therefore, both reach and ability of call frequency" was materially false and misleading for the reasons set forth in, *inter alia*, ¶¶106-168.

294. On February 17, 2017, the Company filed a Form 10-K for the year ended December 31, 2016 ("2016 Form10-K") with the SEC, which provided the Company's full year 2016 financial results and position. The 2016 Form 10-K was signed by Defendants Polymeropoulos, Kelly, Watkins, Bate, Cola, Dugan and Milano. Both Polymeropoulos and Kelly certified that the form "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report." They also certified that "the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the [Company] as of, and for, the periods presented in this report."

295. The 2016 Form 10-K discussed the importance to Vanda of successfully commercializing Fanapt, and stated: "Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt®". The 2016 Form 10-K also discussed the uses and marketing of Fanapt and Hetlioz, and also reimbursement from government programs. In addition to the statements provided in the 2015 Form 10-K, the 2016 Form 10-K added:

> On December 31, 2014, Novartis transferred all the U.S. and Canadian commercial rights to the Fanapt® franchise to Vanda as part of the Settlement Agreement. See Note 3, Settlement Agreement with Novartis, to the consolidated financial statements included in Part II of this annual report on Form 10-K for additional information. In June 2015, we announced positive results from REPRIEVE, a Phase III longterm

> maintenance study that was conducted by Novartis. In May 2016, the FDA approved a supplemental New Drug Application (sNDA) for Fanapt® for the maintenance treatment of schizophrenia in adults.

These statements were materially false and misleading for the reasons set forth in, *inter alia*, ¶¶106-168.

296. The 2016 Form 10-K also discussed the possibility that Vanda could fail to comply with applicable laws and regulations regarding selling and promoting Fanapt, stating: "Failure to comply with government regulations regarding the sale and marketing of our products could harm our business." This statement was materially false and misleading because it failed to disclose that it was not merely possible that failing to comply with applicable laws and regulations regarding selling and marketing Fanapt could disrupt the Company's business and financial performance; this risk had already materialized because Vanda was actively and knowingly engaged in an off-label promotion scheme for Fanapt.

297. On March 21, 2017, Polymeropoulos participated in the 3/21/17 Conference to discuss the Company and its business. During the 3/21/17 Conference, Polymeropoulos stated: *"Fanapt is considered in the US a second line treatment for schizophrenia*." This statement was materially false and misleading for the reasons set forth in, *inter alia*, ¶¶106-168.

298. On May 2, 2017, the Company held a conference call for analysts and investors (the "5/2/17 Call") to discuss Vanda's financial results and performance for the first fiscal quarter of 2017 ("1Q17"). During the 5/2/17 Call, defendant Reverberi stated:

> During the first quarter of 2017, we successfully completed the expansion of the Fanapt U.S. field sales team, and the full team is now in the field promoting the benefits of Fanapt for adult schizophrenia patients with a significant increase in frequency to our target physicians audience.

This statement was materially false and misleading for the reasons set forth in, *inter alia*, ¶¶106-168.

299. On May 3, 2017, Vanda filed a Form 10-Q for 1Q17 (the "1Q17 Form 10-Q"), which was signed by defendants Polymeropoulos and Kelly. The 1Q17 Form 10-Q discusses the importance to Vanda of successfully commercializing Fanapt, and stated: "Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt®". That statement was materially false and misleading for the reasons set forth in, *inter alia*, ¶106-168.

300. The 1Q17 Form 10-Q provided no update to the Company's risk factors since the filing of the 2016 Form 10-K, and stated "[t]here have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2016." That statement was materially false and misleading for the reasons set forth in, *inter alia*, ¶¶106-168.

301. On August 2, 2017, the Company held a conference call for analysts and investors (the "8/2/17 Call") to discuss Vanda's financial results and performance for the second fiscal quarter of 2017 ("2Q17"). During the 8/2/17 Call, defendant Polymeropoulos stated:

> After successfully completing the expansion of our Fanapt field sales team in the first quarter of 2017, the full team has started promoting the benefits of Fanapt for adult schizophrenia patients with an expanded reach and frequency.

This statement was materially false and misleading for the reasons set forth in, *inter alia*, ¶¶106-168.

302. On August 3, 2017, Vanda filed a Form 10-Q for 2Q17 (the "2Q17 Form 10-Q"), which was signed by defendants Polymeropoulos and Kelly. The 2Q17 Form 10-Q discusses the importance to Vanda of successfully commercializing Fanapt, and stated: "Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to

successfully commercialize . . . Fanapt®". This statement was materially false and misleading for the reasons set forth in, *inter alia*, ¶¶106-168.

303. The 2Q17 Form 10-Q provided no update to the Company's risk factors since the filing of the 2016 Form 10-K, and stated: "[t]here have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2016. This statement was materially false and misleading for the reasons set forth in, *inter alia*, ¶¶106-168.

304. On September 13, 2017, defendant Kelly participated at the Morgan Stanley Healthcare Conference (the "9/13/17 Conference") to discuss the Company and its business. During the 9/13/17 Conference, defendant Kelly stated:

> But as we have put more effort behind the product, including what we just did right now, we are now initially seeing the slowing of the decline in what appears to be the degree of stabilization, what we're looking for is growth. And it's our expectation that the reps we have put on board are going to have the ability to return Fanapt back to growth.

305. The statement that "it's our expectation that the reps we have put on board are going to have the ability to return Fanapt back to growth" was materially false and misleading for the reasons set forth in, *inter alia*, ¶¶106-168.

306. On November 8, 2017, Vanda filed a Form 10-Q for the third fiscal quarter of 2017 ("3Q17") (the "3Q17 Form 10-Q"), which was signed by defendants Polymeropoulos and Kelly. The 3Q17 Form 10-Q discusses the importance to Vanda of successfully commercializing Fanapt, and stated: "Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt®". This statement was materially false and misleading for the reasons set forth in, *inter alia*, ¶¶106-168.

307. The 3Q17 Form 10-Q provided no update to the Company's risk factors since the filing of the 2016 Form 10-K, and stated "[t]here have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2016. This statement was materially false and misleading for the reasons set forth in ¶¶106-168.

308. On February 15, 2018, the Company filed a Form 10-K for the year ended December 31, 2017 ("2017 Form 10-K") with the SEC, which provided the Company's full year 2017 financial results and position. The 2017 10-K was signed by Defendants Polymeropoulos and Kelly. The 2017 Form 10-K contained signed SOX certifications by Defendants Polymeropoulos, Kelly, Watkins, Bate, Cola, Dugan and Milano. Both Polymeropoulos and Kelly certified that the form "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report." They also certified that "the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the [Company] as of, and for, the periods presented in this report."

309. The 2017 Form 10-K discussed the uses and marketing of Fanapt and Hetlioz. In addition to the statements provided in the 2015 Form 10-K and 2016 Form 10-K, the 2017 Form 10-K added:

> HETLIOZ®
>
> * * *
>
> Non-24 affects a majority of totally blind individuals, or approximately 80,000 people in the U.S. Blind individuals who develop Non-24 lack the light sensitivity necessary to synchronize the master body clock in the brain with the 24-hour day-night cycle. In sighted individuals, decreased

exposure or sensitivity to light and social and physical activity cues may contribute to a freerunning circadian rhythm. With the high frequency of mental disorders involving social isolation and cases of Non-24 developing after a change in sleep habits, behavioral factors in combination with physiological tendency may precipitate and perpetuate this disorder in sighted individuals. Hospitalized individuals with neurological and psychiatric disorders can become insensitive to social cues, predisposing them to the development of Non-24.

* * *

Fanapt®

* * *

In July 2017, the EMA's Committee for Medicinal Products for Human Use (CHMP) issued a negative opinion recommending against approval of Fanaptum® (oral iloperidone tablets) for the treatment of schizophrenia in adult patients in the E.U. The CHMP was of the opinion that the benefits of Fanaptum® did not outweigh its risks and recommended against marketing authorization. The negative opinion was upheld upon appeal in November 2017.

We received market approval for the commercialization of Fanapt® in Israel in August 2012 and in Mexico in October 2013. Our distribution partners launched Fanapt® in Israel and Mexico in 2014. As of December 31, 2017, we no longer have an active distributor relationship in Mexico.

Schizophrenia is a chronic, debilitating mental disorder characterized by hallucinations, delusions, racing thoughts and other psychotic symptoms (collectively referred to as "positive symptoms"), as well as moodiness, anhedonia (inability to feel pleasure), loss of interest, eating disturbances and withdrawal (collectively referred to as "negative symptoms"), and attention and memory deficits (collectively referred to as "cognitive symptoms"). Schizophrenia develops in late adolescence or early adulthood in approximately 1% of the world's population. Most schizophrenia patients today are treated with drugs known as "atypical" antipsychotics, which were first approved in the U.S. in the late 1980s. These antipsychotics have been named "atypical" for their ability to treat a broader range of negative symptoms than the first-generation "typical" antipsychotics, which were introduced in the 1950s and are now generic. Atypical antipsychotics are generally regarded as having improved side effect profiles and efficacy relative to typical antipsychotics….

Pursuant to a settlement agreement with Novartis, we reacquired the U.S. and Canadian rights to the long-acting injectable (depot) formulation of

> Fanapt®. We are evaluating the commercial opportunity around the depot formulation.

310. The 2017 Form 10-K also discussed reimbursement from government programs, stating in relevant part that: "Sales of our products will be dependent, in large part, on reimbursement from government health administration authorities", that "[c]ertain marketing practices may implicate the federal civil False Claims Act, including promotion of pharmaceutical products for unapproved uses," that"[m]any states also have statutes or regulations similar to the federal laws described above, including state…false claims laws", and that "Our ability to achieved sustained profitability in the future depends, in part, upon…our and our partners' ability to obtain adequate reimbursement coverage for our products[.]"

311. The statements and omissions set forth in the 2015 Form 10-K, 2016 Form 10-K and 2017 Form 10-K were false and misleading because they misrepresented and failed to disclose the following adverse facts pertaining to the Company's business and operations which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that Defendants were: (i) promoting Fanapt and Hetlioz for off-label uses; (ii) overstating Fanapt's efficacy to providers; (iii) downplaying the safety risks associated with Fanapt; (iv) misleading providers about Fanapt's approved dosing schedule; (v) improperly providing titration packets which was in violation of the FDA-approved titration and did not have adequate instructions for use; (vi) promoting Fanapt as a first line therapy; (vii) fraudulently receiving drug reimbursements from the government by abusing Medicare, Medicaid, and Tricare programs, as a result of which scheme Vanda faced a substantial prospect of liability in the Qui Tam Lawsuit; and (viii) causing the Company to garner regulatory scrutiny from the FDA due to its promotional material. Accordingly, Defendants'

statements about Vanda's business, operations and prospects were materially false and misleading and/or lacked a reasonable basis at all relevant times.

312. The 2017 Form 10-K also discussed the possibility that Vanda could fail to comply with applicable laws and regulations regarding selling and promoting Fanapt, stating: "Failure to comply with government regulations regarding the sale and marketing of our products could harm our business." This statement was materially false and misleading because it failed to disclose that it was not merely possible that failing to comply with applicable laws and regulations regarding selling and marketing Fanapt could disrupt the Company's business and financial performance; this risk had already materialized because Vanda was actively and knowingly engaged in an off-label promotion scheme for Fanapt.

313. On April 27, 2018, Defendants caused the Company to file with the SEC its Schedule 14A (the "2018 Proxy Statement"). Defendants Polymeropoulos, Cola, Dugan, Watkins, and former director Milano solicited the 2018 Proxy Statement filed pursuant to Section 14(a) of the Exchange Act, which contained material misstatements and omissions.[13]

314. The 2018 Proxy Statement stated that the Company adopted the Code of Conduct that applies to all directors, officers and employees. This code is available in the Corporate Governance section of our corporate website at www.vandapharma.com. If we make any substantive amendments to this code or grant any waiver from a provision of the code to any applicable executive officer or director, we will promptly disclose the nature of the amendment

[13] Plaintiffs' allegations with respect to the misleading statements in the 2018 Proxy Statement are based solely on negligence; they are not based on any allegation of reckless or knowing misconduct by or on behalf of any of the Defendants, and they do not allege, and do not sound in, fraud. Plaintiffs specifically disclaim any allegations of, reliance upon any allegation of, or reference to any allegation of fraud, scienter, or recklessness about these allegations and related claims.

or waiver on our website." Accordingly, the 2018 Proxy Statement incorporates by reference the information contained in the Code of Ethics.

315. The 2018 Proxy Statement detailed "Risk Oversight" duties:

> Our Board oversees the management of risks inherent in the operation of our business and the implementation of our business strategies. The general categories of risk overseen by the our Board include, without limitation, operational risk, commercial risk, clinical trial risk, capital risk, credit risk, earnings risk, liquidity risk, market risk, price risk, legal/compliance risk, cyber risk and reputational risk. Our Board performs this oversight role by using several different levels of review. In connection with its reviews of the operations and corporate functions of our Company, our Board provides oversight to address the primary risks associated with those operations and corporate functions. In addition, our Board reviews the risks associated with the Company's business strategies periodically throughout the year as part of its consideration of undertaking any such business strategies.
>
> Each committee of our Board also oversees the management of the Company's risk that falls within the committee's areas of responsibility. In performing this function, each committee has full access to management, as well as the ability to engage advisors. Our Chief Financial Officer reports to the Audit Committee and is responsible for identifying, evaluating and implementing risk management controls and methodologies to address any identified risks. In connection with its oversight role, our Audit Committee meets privately with representatives from our independent registered public accounting firm and our Chief Financial Officer.

316. The 2018 Proxy Statement details the duties of the Audit Committee and how it takes affirmative steps concerning integrity:

> Audit Committee
>
> The Audit Committee of the Board oversees the quality and integrity of the Company's financial statements and other financial information provided to the Company's stockholders, the retention and performance of the Company's independent accountants, the effectiveness of the Company's internal controls and disclosure controls, and the Company's compliance with ethics policies and SEC and related regulatory requirements. For these purposes, the Audit Committee, among other duties and powers, (1) approves audit fees for, and selects and reviews the performance of, the Company's independent accountants, (2) reviews reports prepared by management, and attested by the Company's independent accountants with respect to the financial statements contained

> therein, assessing the adequacy and effectiveness of the Company's internal controls and procedures, prior to the inclusion of such reports in the Company's periodic filings as required under the rules of the SEC, (3) reviews the Company's annual and quarterly reports, and associated consolidated financial statements, with management and the independent accountants prior to the first public release of the Company's financial results for such year or quarter, (4) reviews with external counsel any legal matters that could have a significant impact on the Company's financial statements, and (5) establishes and maintains procedures for the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls and auditing matters. Our Audit Committee charter can be found in the Corporate Governance section of our corporate website at www.vandapharma.com. Three directors comprised the Audit Committee as of December 31, 2017: Mr. Dugan (the Chairman of the Audit Committee), Mr. Cola and Mr. Milano. The Audit Committee met nine times during 2017.
>
> The Board annually reviews the Nasdaq listing standards definition of independence for Audit Committee members and has determined that all members of our Audit Committee are independent (as independence is currently defined in applicable Nasdaq listing standards and Rule 10A-3 promulgated under the Exchange Act).

317. The 2018 Proxy Statement was materially misleading because it misrepresented the Board's actual activities with respect to risk management while soliciting votes to re-elect and compensate directors who were breaching their fiduciary duties. A reasonable shareholder would have found the truth to be material when casting his or her vote.

318. The 2018 Proxy Statement was further false and misleading because, despite assertions to the contrary, the Code of Conduct was not followed, as the Director Defendants made and/or caused the Company to make the false and misleading statements discussed herein.

319. In addition, the 2018 Proxy Statement outlined how executive compensation was based on a pay-for-performance basis:

> Compensation Program Philosophy
>
> Our Compensation Committee has determined that our executive compensation program generally targets the executive team's base salaries and total target cash compensation to the 50th percentile of similarly situated named executive officers at our peer group companies and the

> executive team's total equity compensation to approximately the 66th percentile of similarly situated named executive officers at our peer group companies, with the goal of achieving a total compensation mix targeting the 50th percentile of peer group companies over time. The components and target percentiles for our named executive offices is evaluated on a yearly basis by our Compensation Committee. Our Compensation Committee has the flexibility to adjust individual percentile positioning when making individual pay decisions for our named executive officers based on performance. Our Compensation Committee believes that these targets are aligned with competitive market practices, thus enabling us to recruit and retain the talent necessary for the Company to deliver on our business strategy. In addition, this competitive positioning allows for alignment with a ***pay-for-performance philosophy*** with premium levels of cash compensation only awarded for performance that exceeds target levels for pre-determined business and individual goals and equity awards that are a key component of the total rewards package. Our 2017 executive compensation program advances this philosophy.

320. Moreover, Vanda's 2016 Plan itself was depicted as rewarding its participants, including the Individual Defendants, on the basis of performance:

> *Performance Awards.* The 2016 Plan permits the grant of performance-based stock and cash awards that may have qualified as performance-based compensation that is not subject to the $1,000,000 limitation on the income tax deductibility of compensation paid to a covered named executive officer imposed by Section 162(m) prior to the enactment of the 2017 Tax Cuts and Jobs Act. To help assure that the compensation attributable to performance-based awards would have qualified, our compensation committee could have structured awards prior to November 2, 2017 so that stock or cash would have been issued or paid pursuant to such award only after the achievement of certain pre-established performance goals during a designated performance period.
>
> A performance stock award is a stock award that is payable (including that may be granted, may vest or may be exercised) contingent upon the achievement of pre-determined performance goals during a performance period. A performance stock award may require the completion of a specified period of continuous service. Performance stock awards may be subject to one or more minimum performance requirements, and will not commence vesting until the grantee has completed at least one year of performance and/or service. The length of any performance period, the performance goals to be achieved during the performance period, and the measure of whether and to what degree such performance goals have been attained will generally be determined by our compensation committee, except that the plan administrator also may make any such determinations

to the extent that the award is not intended to comply with Section 162(m) of the Code. In addition, to the extent permitted by applicable law and the performance stock award agreement, the plan administrator may determine that cash may be used in payment of performance stock awards.

A performance cash award is a cash award that is payable contingent upon the achievement of pre-determined performance goals during a performance period. A performance cash award may require the completion of a specified period of continuous service. The length of any performance period, the performance goals to be achieved during the performance period and the measure of whether and to what degree such performance goals have been attained will generally be determined by our compensation committee, except that the plan administrator also may make any such determinations to the extent that the award is not intended to comply with Section 162(m) of the Code. The plan administrator may specify the form of payment of performance cash awards, which may be cash or other property, or may provide for a participant to have the option for his or her performance cash award, or such portion thereof as the plan administrator may specify, to be paid in whole or in part in cash or other property.

In granting a performance award intended to qualify as "performance-based compensation" under Section 162(m) of the Code, our compensation committee will set a period of time, or a performance period, over which the attainment of one or more goals, or performance goals, will be measured. Within the time period prescribed by Section 162(m) of the Code (no later than the earlier of the 90th day of a performance period and the date on which 25% of the performance period has elapsed, and in any event at a time when the achievement of the performance goals remains substantially uncertain), our compensation committee will establish the performance goals, based upon one or more criteria, or performance criteria, enumerated in the 2016 Plan and described below. As soon as administratively practicable following the end of the performance period, our compensation committee will certify in writing whether the performance goals have been satisfied.

Performance goals under the 2016 Plan are based on any one or more of the following performance criteria: (1) earnings (including earnings per share and net earnings); (2) earnings before interest, taxes and depreciation; (3) earnings before interest, taxes, depreciation and amortization, or EBITDA; (4) growth of earnings before interest and taxes; (5) EBITDA margin, adjusted EBITDA margin, or adjusted EBITDA; (6) total stockholder return; (7) return on equity or average stockholder's equity; (8) return on assets, net assets, investment, or capital employed; (9) stock price; (10) margin (including gross margin); (11) income (before or after taxes); (12) net income or operating income; (13)

> operating income after taxes; (14) pre-tax profit or after-tax profit; (15) operating cash flow; (16) revenue or sales (including revenue or sales targets); (17) increases in revenue or product revenue; (18) expenses and costs (including expenses and cost reduction goals); (19) improvement in or attainment of working capital levels or expense levels; (20) economic value added (or an equivalent metric); (21) market share; (22) cash flow; (23) cash flow per share; (24) earnings per share; (25) share price or share price performance; (26) debt reduction; (27) implementation or completion of projects or processes; (28) customer satisfaction; (29) number of customers; (30) stockholders' equity; (31) return on stockholders' equity; (32) capital expenditures; (33) debt levels; (34) operating profit or net operating profit; (35) workforce diversity; (36) growth of net income or operating income; (37) billings; (38) days sales outstanding; and (39) to the extent that an award is not intended to comply with Section 162(m) of the Code, other measures of performance selected by the plan administrator.
>
> Performance goals may be based on a company-wide basis, with respect to one or more business units, divisions, affiliates or business segments and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Under the 2016 Plan, unless specified otherwise by the board of directors (i) in the award agreement at the time the award is granted or (ii) in such other document setting forth the performance goals at the time the performance goals are established, the board of directors will appropriately make adjustments in the method of calculating the attainment of performance goals for a performance period as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects, as applicable, for non-U.S. dollar denominated performance goals; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; and (5) to exclude the effects of any "extraordinary items" as determined under generally accepted accounting principles. In addition, our compensation committee (or, if not required for compliance with Section 162(m) of the Code, the plan administrator) retains the discretion to reduce or eliminate the compensation or economic benefit due upon the attainment of any performance goals and to define the manner of calculating the performance criteria it selects to use for a performance period.

321. The 2018 Proxy Statement harmed Vanda by preventing the Company's shareholders from making an informed decision as to whether to approve executive compensation on an advisory basis and whether to approve the amendment and restatement of the Company's 2016 Plan, which

provided additional shares to the plan for additional compensation to the Company's officers and directors, including the Defendants. Vanda stockholders would never have voted to approve executive compensation on an advisory basis and to amend and restate the Company's 2016 Plan had they known the Defendants were knowingly aware of, or recklessly disregarded, the off-label promotion scheme for Fanapt and Hetlioz and that Vanda refused to conduct a safety trial for tradipitant that was needed for it to ultimately received FDA approval. The Defendants' actions were contrary to the Company's stated compensation practices in the 2018 Proxy Statement and sought to award compensation not based on performance as represented, but rather on false and misleading statements that depicted a rosy picture of the Company's financial condition.

322. The 1Q18 Form 10-Q signed by defendants Polymeropoulos and Kelly discusses the importance to Vanda of successfully commercializing Fanapt, and stated: "Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt®". This statement was materially false and misleading for the reasons set forth in, *inter alia*, ¶¶106-168.

323. The 1Q18 Form 10-Q provided no update to the Company's risk factors since the filing of the 2017 Form 10-K, and stated:

> There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2017.

This statement was materially false and misleading for the reasons set forth in, *inter alia*, ¶¶106-168.

324. On August 1, 2018, the Company held a conference call for analysts and investors (the "8/1/18 Call") to discuss Vanda's financial results and performance for the

second fiscal quarter of 2018 ("2Q18"). During the 8/1/18 Call, defendant Polymeropoulos stated:

> I also want to remind that in June, we undertook a reorganization of the Fanapt sales force that promote HPI, and that was a very significant reorganization. And we're in the midst of hiring in full the sales force back up to a number of 115 after we changed about 35-or-so sales representatives. So we do expect that this reorganization will affect the production of new scripts during that reorganization, but we do not expect the reorganization to affect the overall performance of the third quarter or beyond. And we believe that this will strengthen, actually, our presence in the psychiatrist office in the promotion of both Fanapt and HETLIOZ.

325. The statement referenced in the previous paragraph that "we believe that this will strengthen, actually, our presence in the psychiatrist office in the promotion of both Fanapt and Hetlioz" was materially false and misleading for the reasons set forth in, *inter alia*, ¶¶105-167.

326. On August 2, 2018, Vanda filed its 2Q18 Form 10-Q, which was signed by defendants Polymeropoulos and Kelly. The 2Q18 Form 10-Q discusses the importance to Vanda of successfully commercializing Fanapt, and stated, in pertinent part, that: "Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize… Fanapt®". This statement was materially false and misleading for the reasons set forth in, *inter alia*, ¶¶106-168.

327. The 2Q18 Form 10-Q provided no update to the Company's risk factors since the filing of the 2017 Form 10-K, and stated, in pertinent part, that:

> There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2017.

This statement was materially false and misleading for the reasons set forth in, *inter alia*, ¶¶106-168.

328. On September 12, 2018, Defendant Kelly participated in the Morgan Stanley Healthcare Conference to discuss the Company and its business. During the conference, Defendant Kelly stated:

> And I'd say that this core blind business has been a great methodical growth story. But something changed last year in the fourth quarter. And what changed was a new initiative where we began targeting sighted individuals with psychiatric comorbidities who had Non-24. And what start us down this path was the work we were doing with Fanapt or atypical antipsychotic, where we're calling on 10,000 psychiatrists. We decided after expanding our Fanapt field force last year to introduce HETLIOZ to that group, and the response has been incredible. Wesaw a more than doubling of our scripts, and we shared with investors, both in the first quarter, second quarter, that we had all-time highs of both scripts and new patient starts, and it's being driven, the majority of it, by this sighted strategy. And so fairly unusual to have a product 5 years in that is continuing its core methodical growth and then add on top of it a new diversified approach to grow in the business.
>
> * * *
>
> And when we developed HETLIOZ for Non-24, our focus was on totally blind individuals, these individuals who lost that light perception, along with it, lost what is considered to be the standard mechanism to reset your body clock every day.

329. The statement referenced in the previous paragraph that "[w]e decided after expanding our Fanapt field force last year to introduce Hetlioz to that group, and the response has been incredible" was materially false and misleading because the Defendants failed to adequately disclose an accurate portrayal of the Company's efforts to market and sell Hetlioz during the Relevant Period.

330. On November 7, 2018, the Company held a conference call for analysts and investors to discuss Vanda's financial results and performance for 3Q18. During the call, Defendant Polymeropoulos stated:

> HPI now is a year old, the program, and what is impressive is the significant, continuous new demand, new scripts written by psychiatrists

> in the HPI initiative. While Jim is correct that the PDP part of the business, which is mostly blind individuals, these are people we have opted into the database, continues to be a big driver and source. However, in new demand, and that is -- the definition of demand here is new scripts written, HPI continues to significantly outstrip the demand of PDP. So with that, one would have expected to actually saw even bigger growth than the 34%, which is nonetheless impressive. So why we have not seen even bigger growth? The HPI business, as we characterized before, has created a demand 2 to 3x higher than the PDP. However, the resistance by insurers on filling out the scripts, although it is the only indication and there is no other drug available for these patients, continues to be strong. We're working with our patients, we're working with the doctors to impress upon these insurers that this drug is necessary. We're making a lot of progress. But if we were to match the demand generated with fill, of course, these numbers would have been much, much bigger.

331. The statement referenced in the previous paragraph that "what is impressive is the significant, continuous new demand, new scripts written by psychiatrists in the HPI initiative" was materially false and misleading because the Defendants failed to adequately disclose an accurate portrayal of the Company's efforts to market and sell Hetlioz during the Relevant Period.

332. On November 7, 2018, Vanda filed the 3Q18 Form 10-Q, which was signed by defendants Polymeropoulos and Kelly. The 3Q18 Form 10-Q discusses the importance to Vanda of successfully commercializing Fanapt, and stated: "Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize… Fanapt®". This statement was materially false and misleading for the reasons set forth in, *inter alia*, ¶¶106-168.

333. The 3Q18 Form 10-Q provided no update to the Company's risk factors since the filing of the 2017 Form 10-K, and stated:

> There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2017.

This statement was materially false and misleading for the reasons set forth in, *inter alia*, ¶¶106-168.

334. On December 3, 2018, Vanda filed a Form 8-K, which stated:

> Vanda expects to meet with regulatory authorities in the near future to further define and confirm the path towards registration of tradipitant in the treatment of patients with gastroparesis.

335. By speaking about Vanda's interactions with the FDA to discuss future clinical trials for tradipitant related to gastroparesis, the Defendants had a duty to speak fully and truthfully. Because the Defendants failed to disclose that Vanda was informed by the FDA on the conference call held on May 15, 2018 that the Company's refusal to conduct a nine-month non-rodent toxicity study to ensure that tradipitant is safe in humans meant that the FDA would impose a clinical hold on any tradipitant trial over three months in duration, this statement omitted material information from Vanda's investors, thereby rendering this statement materially false and misleading. The Defendants' failure to adequately disclose an accurate portrayal of the status of tradipitant clinical trials during the Relevant Period rendered this statement materially false and misleading.

336. Also, on December 3, 2018, Defendants Polymeropoulos and Kelly also hosted a conference call with analysts and investors to announce positive results from the 2301 Study. During the call, Defendant Polymeropoulos stated:

> Finally, we believe that if these robust efficacy results with a well-tolerated chronic treatment safety profile are further confirmed in future studies, tradipitant has the potential to become a first-line pharmacological option in the treatment of patients with gastroparesis and the first such agent in 40 years. The detailed results of the study are expected to be presented in our cabin meetings and peer-reviewed publications. We will also be meeting with regulatory authorities in the near future to further define and confirm the path towards registration of tradipitant in the treatment of patients with gastroparesis.

* * *

> Pete, certainly, we want to continue to evaluate the effectiveness of the drug in the broad population of gastroparetic patients. However, I would say while we have some very good ideas of potential designs and population of patients, we need to spend a little more time understanding these study results, but also sit down with key opinion leaders, investigators, and certainly, the Food and Drug Administration to find out the fastest to market. And the reason for that is we recognize that what tradipitant has shown in this Phase II study, can be an extremely useful therapeutic tool for patients.
>
> * * *
>
> Analyst (Esther Rajavelu, Oppenheimer): "And then my last question. Are you -- do you anticipate having to do a long-term safety study on -- in the gastroparesis population given the chronic nature of the condition and the treatment?
>
> Defendant Polymeropoulos: "Absolutely, I would be very appropriate to do so. And in fact, we have a 12-month protocol, which we'll be implementing shortly.

337. The statements referenced in the previous paragraph that "[w]e will also be meeting with regulatory authorities in the near future…" and "sit down with…the Food and Drug Administration to find out the fastest to market" were materially false and misleading because, by speaking about Vanda's interactions with the FDA to discuss future clinical trials for tradipitant related to gastroparesis, the Defendants had a duty to speak fully and truthfully. Because the Defendants failed to disclose that Vanda was informed by the FDA on the conference call held on May 15, 2018 that the Company's refusal to conduct a nine-month non-rodent toxicity study to ensure that tradipitant is safe in humans meant that the FDA would impose a clinical hold on any tradipitant trial over three months in duration, this statement omitted material information from Vanda's investors, thereby rendering this statement materially false and misleading. The Defendants' failure to adequately disclose an accurate portrayal of the status of tradipitant clinical trials during the Relevant Period rendered this statement materially false and misleading.

338. Further, the statements referenced in the paragraph before last that "we have a 12-month protocol, which we'll be implementing shortly" was materially false and misleading when made because it misrepresented the following facts, which the Defendants knew, or recklessly disregarded: (i) Vanda could not implement a 12-month protocol for tradipitant shortly because the FDA told Vanda on the conference call held on May 15, 2018 that the Company had to first conduct a nine-month non-rodent study to ensure that tradipitant is safe to use in humans; (ii) Vanda was unwilling at all relevant times to conduct the required nine-months safety study; and (iii) Vanda intended to sue the FDA if the FDA placed the expected clinical trial holds on any tradipitant studies over three months in length.

THE DEFENDANTS' BREACHES OF DUTY BECOME APPARENT

339. On October 22, 2018, the FDA sent Vanda a warning letter which was addressed to Defendant Polymeropoulos (the "Warning Letter"). The Warning Letter was in response to the FDA's review of Vanda's website which the FDA found "false and misleading" due to its failure to disclose risks of the Fanapt and Hetlioz and in violation of the FD&C Act. The FDA raised its concerns with the promotional materials for these drugs. The Warning Letter states that "This webpage is false or misleading in that it presents information about the benefits of Fanapt and Hetlioz, but fails to include any risk information about either drug. Thus, the webpage misbrands Fanapt and Hetlioz within the meaning of the Federal Food, Drug and Cosmetic Act (FD&C Act) and makes their distribution violative. 21 U.S.C. 352(a) & (n); 321(n), 331(a). See 21 CFR 202.1(e)(5). This violation is concerning from a public health perspective because it creates a misleading impression about the safety of Fanapt and Hetlioz. Of particular concern is that Fanapt is a drug that bears a Boxed Warning due to serious, life-threatening risks, including

increased mortality in elderly patients with dementia-related psychosis, as well as numerous other warnings."

340. The Warning Letter further explains the standard for determination of whether promotional materials are misleading and emphasizes that "The webpage includes claims and/or representations about the uses and/or benefits of Fanapt and Hetlioz; however, it fails to communicate any risk information about the products…. By omitting the risks associated with Fanapt and Hetlioz, the webpage fails to provide material information about the consequences that may result from the use of the drugs and creates a misleading impression about the drugs' safety. This misleading presentation is especially problematic from a public health perspective due to the serious and potentially life-threatening risks associated with the drugs, such as those contained in Fanapt's Boxed Warning."

341. On this news, shares of Vanda fell $2.00 per share or over 9% over the next two trading days to close at $20.00 per share on October 24, 2018.

342. On February 4, 2019, the Qui Tam Lawsuit, which disclosed Vanda's years of fraudulent promotion of Fanapt and Hetlioz as well as its scheme to defraud the government with fraudulent reimbursements, was unsealed.

343. On February 11, 2019, the Aurelius Report summarized the Qui Tam Lawsuit and provided a link to the complaint. In addition to the information provided in the Qui Tam Lawsuit, the Aurelius Report further stated in relevant part:

> Our research indicates that Vanda has had an extremely difficult time attracting and keeping blind patients on Hetlioz, the population the drug was tested on and designed to treat. In order to meet growth targets, we believe Vanda's "secret sauce" is a product of Polymeropoulos harnessing the Fanapt sales force to begin selling Hetlioz to psychiatrists as a sleep aid alternative to Ambien and Lunesta for sighted patients. The principal problem is that taxpayers appear to be on the hook for Polymeropoulos' alleged shenanigans.

> Non-24 is so rare that Vanda had to cut patient enrollment of its FDA trials of Hetlioz in half because it could not identify enough patients with the condition. This makes it exceedingly difficult for Vanda to sell Hetlioz to patients with Non-24, which one former rep described as the classic "needle in the haystack" exercise. After launch in 2014, Vanda's strategy was centered on building awareness by sending sales reps to blind community centers and running tv and radio spots to target friends and family members, an effort that initially appears to have been somewhat fruitful.
>
> But our research also indicates that Hetlioz has unfavorable levels of front-end patient churn, meaning patients who begin treatment often drop off in the first six months. One explanation is that the drug simply doesn't work very well for some patients.
>
> * * *
>
> We also examined data from the FDA Adverse Event Reporting System ("FAERS"), which contains information on medication error reports submitted to the FDA. The single most frequently reported adverse event is the complaint of "drug ineffective" which, when combined with similar complaints about efficacy, totals 888 complaints since 2014, an amount which exceeds the number of patients currently on Hetlioz. In fact, questions about Hetlioz's efficacy date back to 2013, when Health Care columnist Adam Feuerstein identified "a disturbingly large number of irregularities and red flags" related to Vanda's clinical trials of Hetlioz.

344. On this news, shares of Vanda fell $0.95 per share or over 5% to close at $18.00 per share on February 11, 2019.

345. Further, as a direct result of Defendants Polymeropoulos and Kelly's omissions of the abovementioned material information and misleading statements about Vanda's business, operations and prospects, the Company is now the subject of the Securities Class Action.

346. As a result of the Defendants' misconduct, Vanda sustained damages, including but not limited to costs and expenses incurred in connection with the legal action taken against the Company.

THE DEFENDANTS BREACHED THEIR FIDUCIARY DUTIES

A. The Officer Defendants Breached Their Fiduciary Duties

347. The Officer Defendants have breached their duties of care and loyalty by knowingly violating the FCA, state false claims acts, the FD&C Act and federal securities laws.

348. The Officer Defendants, especially Polymeropoulos and Reverberi, have actual knowledge of the fraudulent marketing and promotion of Fanapt and Hetlioz for off-label uses and actively participated in this scheme.

349. As discussed above, Defendant Polymeropoulos built the fraudulent marketing scheme from scratch and participated in every stage of the misconduct.

350. Defendant Polymeropoulos instructed sales representatives to promote Fanapt and Hetlioz for off-label use and refused to alter the marketing strategy designed to promote Fanapt as a cure for Akathisia, resulting in noisy resignations of Gibbs and Holland, who vehemently protested this marketing strategy. Defendant Polymeropoulos also directed the sales representatives to promote Fanapt as a first line treatment despite FDA's limitation, instructed the sales representatives to promote Fanapt as a once-a-day medication despite being FDA approved as a twice-a-day medication, implemented sales techniques to downplay or completely omit safety information for Fanapt and Hetlioz, and knowingly concealed the fraudulent scheme to misuse Fanapt copay cards.

351. Defendant Polymeropoulos was also perfectly aware that he was building an illegal fraudulent scheme which could result in legal actions from the government. To conceal this misconduct, Vanda's head of compliance, Arnold, instructed the RBLs not to describe their sales effort as "push"[ing] doctors to prescribe Fanapt in their sales report.

352. Moreover, Defendant Polymeropoulos turned Vanda into an increasingly nepotistic organization by transferring authority of key departments to his children. His son, Christos Polymeropoulos, started working in Vanda as a Medical Director in October 2014, and

was promoted to Pharmacovigilance Medical Director and Program Lead effective March 1, 2017. His daughter, Katerina Polymeropoulos, started as a Health Educator on September 29, 2014, and was promoted to Marketing Coordinator in March 2017. His other son, Vasilios Polymeropoulos, started working in Vanda as a Director of Medical Analytics on February 12, 2018.

353. Defendant Reverberi has always been an active participant in the misconduct. He even threatened the sales representatives to meet the unrealistic sales goals, which can only be achieved by promoting Fanapt for off-label uses and caused recurring issues between the RBLs and Vanda senior management.

354. Moreover, Defendant Reverberi is not new to this kind of off-label marketing and promotion scheme. Prior to joining Vanda, Defendant Reverberi served as Senior Vice President, International Specialty Pharma at Shire Pharmaceuticals ("Shire"). From 2009 to 2013, Reverberi led Shire's Internal Medicine Global Business Unit where his responsibilities included the management of the U.S. Sales and Marketing teams. During his tenure, one of his colleagues, Shire's former Vice President, Gerardo Torres, along with other Shire former employees, brought qui tam actions against Shire alleging violations of the FCA for allegedly making false and unsupported claims related to Adderall XR, Vyvanse, Daytrana, and promoting off-label uses of its two drugs, Pentasa, and Lialda. As the Vice President who led Shire's Sales and Marketing team, Defendant Reverberi must have participated in the fraudulent promotion or at least had actual knowledge of the violations at Shire. After joining Vanda, Defendant Reverberi continued to market and promote drugs for off-label uses despite knowing the damage that would be done to the Company.

355. As a direct result of the Officer Defendants' misconduct, the Company is now the subject of the Qui Tam Lawsuit and the Securities Class Action and sustained damages, including, but not limited to the costs and expenses incurred in defending the Qui Tam Lawsuit and the Securities Class Action.

356. Moreover, Defendants Polymeropoulos and Kelly breached their duty of care and loyalty by making materially false and/or misleading statements, as well as omitting disclosure of material adverse facts about the Company's business, operations, and prospects. Specifically, they failed to disclose to investors that: (i) Vanda was engaged in a fraudulent scheme in which the Company promoted the off-label use of Fanapt and Hetlioz; (ii) Vanda was fraudulently receiving drug reimbursements from the government by abusing Medicare, Medicaid, and Tricare programs; (iii) as a result of the scheme, Vanda faced a Qui Tam Lawsuit from the government; (iv) Vanda's promotional materials for Fanapt and Hetlioz were false and misleading, garnering regulatory scrutiny from the FDA; and (v) as a result, Defendants' statements about Vanda's business, operations and prospects were materially false and misleading and/or lacked a reasonable basis at all relevant times.

357. Each director and officer of the Company owes to Vanda and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets, and the highest obligations of fair dealing. Here, the Officer Defendants willfully ignored their obligations under federal and state laws, FDA regulations and their duty to run Vanda in a legal and ethical manner under the Code of Conduct. Defendants failed to make a good faith effort to correct the problems or prevent their recurrence. To the contrary, they actively participated in ongoing violations of laws and

regulations. Therefore, the Officer Defendants breached their fiduciary duties willfully and consciously.

B. The Board Consciously Failed to Carry Out Oversight Duties

358. The directors and officers enabled and created an environment in which Vanda continued to place profit over public health and following the law. The Board failed to maintain or improve its controls and has not shifted its focus to placing safety of consumers and the people of the United States above its own short-term profit. Instead, the Board allowed Vanda to repeatedly violate the FCA, state false claims acts, and federal securities laws, and ignore its own internal policies for abiding by the laws and regulations that apply to advertising and promotion of its products, including rules of the FDA and other regulatory authorities. As such, Plaintiffs were left with no choice but to bring this derivative action on behalf of Vanda to remedy the directors' and officers' misconduct. Unless the Court acts to change the culture of Vanda, the alleged misconduct will continue to cause substantial financial and reputational harm to Vanda.

359. The facts sufficiently support a reasonable inference that there was a conscious lack of any system of Board-level controls and reporting. The Board consciously left reporting and controls completely to the discretion of management to determine what controls were necessary and sufficient and when and whether to bring information to the Board.

360. It appears that there is no Board committee that addresses drug promotion or safety. Had the Board implemented a regular process or protocols to keep the Board apprised of drug promotion or safety compliance practices and risks, it could have taken timely preventive actions.

361. Moreover, during the key period during which the alleged misconduct happened, the Board received noisy resignations from four senior officers - Holland, Gibbs, Senior Vice

President and Chief Medical Officer Paolo Baroldi ("Baroldi"), and Senior Vice President, General Counsel and Secretary Richard L. Gulino ("Gulino") - which raised or should have raised alarms about the Company's marketing practices. The Board's inaction shows that the Board either recklessly disregarded the years-long violations or completely failed to monitor and oversee compliance with the laws and regulations that apply to Vanda's business, raising a reasonable inference that the Board received little information about drug marketing and promotion by management, and that the Board meetings lacked any regular discussion of relevant issues.

362. During the time of the wrongful conduct, the Board consisted of Polymeropoulos, Watkins, Cola, Bate, Dugan, Milano and Pien.

363. As an active participant in the fraudulent scheme, Defendant Polymeropoulos has actual knowledge of the misconduct alleged herein.

364. Defendant Watkins, as the Chairman of the Board, failed to implement the appropriate disciplinary action for any officer or director who violated the Code of Conduct. He has also failed to monitor and oversee corporate governance and compliance with the Code of Conduct.

365. As members of the Nominating/Corporate Governance Committee, Defendants Watkins and Dugan failed to carry out their obligation to monitor and oversee corporate governance and abide by Code of Conduct. Even if they did not personally participate in the alleged misconduct, they had or should have actual knowledge of the years-long violations. Not only did they fail to take any disciplinary action against the persons who actually participated in the scheme, they also failed to oversee the operations of Vanda. Therefore, Defendants Watkins and Dugan breached their fiduciary duty by failing to act where they have a known obligation to act.

366. Defendants Cola, Milano and Dugan breached their fiduciary duty during their tenure on the Audit Committee. As set forth above, the Audit Committee's charter imposes specific duties on its members to ensure compliance with laws, regulations, and internal policies. As members of the Audit Committee, they allowed or permitted false and misleading statements to be disseminated in the Company's SEC filings and other disclosures and otherwise failed to ensure that adequate internal controls were in place regarding the deficiencies described above. Therefore, Defendants Cola, Milano, and Dugan violated their fiduciary duties to act in good faith to address the violations of law complained of herein.

DAMAGES

367. As a result of the Defendants' misconduct, Vanda and its shareholders have sustained and will continue to sustain damages and injuries for which they have no adequate remedy at law. Vanda is currently facing significant liability as a result of the Qui Tam Lawsuit. The Company has also incurred, and will continue to incur, substantial legal fees and expenses in defending the Qui Tam Lawsuit.

368. Vanda is also the subject of a Securities Class Action as a result of Defendants' misconduct. The improper and misleading statements damaged the Company's credibility and future prospects as evidenced by the collapse of the Company's stock price following the disclosure of the truth. In addition, as a direct and proximate result of the Defendants' actions, Vanda has expended, and will continue to expend, significant sums of money in defending the Securities Class Action.

DEMAND FUTILITY

369. Plaintiffs bring this action derivatively on behalf of Vanda to redress injuries which are the direct and proximate result of breaches of fiduciary duty and other misconduct by the Defendants.

370. Plaintiffs are current owners of the Company's stock and have each continuously owned shares of the Company's stock at all relevant times. Plaintiffs understand their obligation to hold Company stock throughout the duration of this action and are prepared to do so.

371. Plaintiffs will adequately and fairly represent the interests of Vanda in enforcing and prosecuting its rights and have retained counsel competent and experienced in stockholder derivative litigation.

372. Plaintiffs did not make a demand on the Board prior to instituting this stockholder derivative suit because a pre-suit demand upon the Board would be a futile, wasteful and useless act.

373. At the time this case was commenced, the Board consisted of five directors, four of whom are among the Director Defendants: Polymeropoulos, Watkins, Cola, and Dugan.

374. As discussed above, Vanda's executives knowingly and consciously violated the FCA, state false claims acts, the FD&C Act and federal securities laws. The Board implemented and oversaw a business strategy that resulted in widespread and repeated violations of the law. Promoting drugs for off-label use, submitting fraudulent bills to the government, making public misrepresentations and/or failing to disclose material facts are not legally protected business decisions and such conduct can in no way be considered a valid exercise of business judgment.

375. The Director Defendants were responsible for a sustained or systemic failure of the Board to exercise oversight. The sustained failure of the Board to ensure effective corporate

governance and compliance with the law can only have been a result of Defendants' knowing breach or reckless disregard for their fiduciary duties. The Director Defendants either knew or should have known of the years-long violations and false and misleading statements that were issued on the Company's behalf and took no steps in a good faith effort to prevent or remedy that situation.

376. The Board devoted patently inadequate time or consciously disregarded compliance with federal and state laws and regulations. The Director Defendants' breach of their fiduciary duties of good faith and loyalty, as well as the Code of Conduct, damaged the Company. The Director Defendants' decision not to act was not made in good faith and was contrary to the best interests of the Company.

377. Therefore, the Director Defendants each face a substantial likelihood of personal liability for their acts in connection with these actions, rendering a demand upon them futile.

A. Demand on Defendant Polymeropoulos is Futile

378. Defendant Polymeropoulos served as President, Chief Executive Officer and director of Vanda during the Relevant Period. He faces a substantial likelihood of liability based on the misconduct alleged above.

379. As alleged above, Defendant Polymeropoulos breached his duty of care and loyalty by knowingly violating the FCA, state false claims acts, the FD&C Act and applicable regulatory and ethical guidance by submitting fraudulent bills to the government, promoting off-label marketing and other prohibited marketing strategies. Defendant Polymeropoulos also knowingly or recklessly made or disseminated made false and/or misleading statements and/or failed to disclose material information regarding Vanda's fraudulent promotion scheme and abuse of Medicare, Medicaid, and Tricare programs, thereby violating the federal securities laws.

380. As such, Defendant Polymeropoulos faces a substantial likelihood of liability for violating the federal securities laws and breaching his fiduciary duty of due care by causing the Company to violate the FCA, state false claims acts, the FD&C Act and the securities laws.

381. For these reasons, demand is futile against Defendant Polymeropoulos.

B. Demand on Defendants Watkins, Cola, and Dugan is Futile

382. From 2015 to early 2018, four key executives resigned. Vanda's Vice President and Director of Marketing, Holland, resigned in January 2016 after vehemently protesting Vanda's fraudulent marketing strategy. Gibbs, Vanda's Senior Vice President and CCO, also resigned after the internal disputes. In 2017, Vanda's Senior Vice President and Chief Medical Officer, Baroldi, resigned as an officer and employee of the Company. In 2018, Vanda's Senior Vice President, General Counsel and Secretary, Gulino, resigned as an officer and employee of the Company.

383. Defendants Watkins, Cola, and Dugan (as well as Defendant Polymeropoulos) had actual knowledge of these resignations. At a minimum, Holland and Gibbs's resignations after protesting Vanda's fraudulent marketing scheme did or should have put the Board on notice of the alleged misconduct. The Board's inaction evidences that it devoted inadequate time to oversight or consciously disregarded its duty of care.

384. Moreover, Defendants Watkins and Dugan are conflicted from considering a demand because they each face substantial likelihood of liability as members of the Nominating/Corporate Governance Committee. As detailed above, the Corporate Governance Committee charter and Code of Conduct required the members of the committee to monitor and oversee corporate governance. Not only did they fail to take any disciplinary actions against the persons who participated in this scheme, they also failed to oversee the operations of Vanda.

Therefore, Defendants Watkins and Dugan face a substantial likelihood of liability for their breach of fiduciary duty and any demand upon them is futile.

385. Defendants Cola and Dugan are also conflicted from considering demand because they each face substantial likelihood of liability as members of the Audit Committee. As set forth above, the Audit Committee's charter imposes specific duties on its members to ensure compliance with laws, regulations and internal policies. As members of the Audit Committee, they allowed or permitted false and misleading statements to be disseminated in the Company's SEC filings and other disclosures, and otherwise failed to ensure that adequate internal controls were in place regarding the deficiencies described above. Therefore, Defendants Cola and Dugan face a substantial likelihood of liability for their breach of fiduciary duties and any demand upon them is futile.

386. Additionally, Defendant Cola is incapable of impartially considering a demand to commence and vigorously prosecute this action due to his long-standing, overlapping business relationships. In particular, Cola served as President of Shire's Specialty Pharmaceuticals business from 2007 until April 2012. Defendant Cola joined Shire in July 2005 as Executive Vice President for Global Therapeutic Business Units and Portfolio Management prior to being named President of the Specialty Pharmaceuticals business.

387. Defendant Reverberi served as Senior Vice President, International Specialty Pharma at Shire. In addition to his International Specialty Pharma responsibilities, from 2009 to 2013, Reverberi led Shire's Internal Medicine Global Business Unit. Prior to this position, he was General Manager, Italy at Shire. Accordingly, there is reasonable doubt that defendant Cola would vote to initiate litigation against defendant Reverberi due to their long-standing business relationships. Demand is therefore futile as to defendant Cola.

388. Defendant Milano served as Chairman, President, and Chief Executive Officer of ViroPharma, which was acquired by Shire on January 2, 2014. Defendant Milano joined ViroPharma in 1996 and served as Vice President, Chief Financial Officer, and Treasurer from 1997 to 2006 prior to becoming Chief Executive Officer. Accordingly, there is reasonable doubt that defendant Milano would vote to initiate litigation against Defendant Reverberi due to their long-standing business relationships. Demand is therefore futile as to defendant Milano.

CAUSES OF ACTION

Count I: Breach of Fiduciary Duty

389. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

390. The Defendants all owed and owe fiduciary duties to Vanda. By reason of their fiduciary relationships, Defendants specifically owed and owe Vanda the highest obligation of good faith and loyalty in the administration of the affairs of Vanda, including assuring that Vanda complied with state and federal laws and FDA regulations. The Board also had specific fiduciary duties as defined by the Company's corporate governance documents and principles that, had they been discharged in accordance with the Board's obligations, would have prevented the misconduct and consequential harm to Vanda alleged herein.

391. The Defendants willfully ignored their obligations under state and federal laws and regulations, Vanda's internal controls and numerous warnings and government investigations and warning. Defendants failed to make a good faith effort to correct the problems or prevent their recurrence.

392. The Defendants consciously breached their fiduciary duties by affirmatively and repeatedly failing to cause the Company to maintain effective controls against promoting drugs for off-label use and defrauding government-funded healthcare programs.

393. The Defendants, by their actions and by engaging in the wrongdoing described herein, abandoned and abdicated their responsibilities and duties with regard to prudently managing the business of Vanda in a manner consistent with the duties imposed upon them by law.

394. As a direct and proximate result of the Defendants' conscious failure to perform their fiduciary obligations, Vanda has sustained significant damages. Such damage includes, among other things, the substantial penalties, fines, costs associated with defending the Qui Tam Lawsuit and the Securities Class Action, severe damage to the share price of the Company, sales suspension and expenses described herein.

395. As a result of the misconduct alleged herein, the Defendants are liable to the Company.

Count II: Gross Mismanagement

396. Plaintiffs repeat and re-allege each and every allegation above as if set forth fully herein.

397. By their actions alleged herein, the Defendants, either directly or through aiding and abetting, abandoned and abdicated their responsibilities and fiduciary duties with regard to prudently managing the assets and business of the Company in a manner consistent with the operations of a publicly held corporation.

398. As a direct and proximate result of the Defendants' gross mismanagement and breaches of duty alleged herein, the Company has sustained damages in excess of hundreds of millions of dollars.

399. Because of the misconduct and breaches of duty alleged herein, the Defendants are liable to the Company.

Count III: Unjust Enrichment

400. Plaintiffs repeat and re-allege each and every allegation above as if set forth fully herein.

401. By their wrongful acts and omissions, the Defendants were unjustly enriched at the expense of Vanda. as a result of the compensation and director remuneration they received while breaching fiduciary duties owed to Vanda.

402. Plaintiffs, on behalf of Vanda, have no adequate remedy at law.

Count IV: Violations of Section 10(b) of the Exchange Act and Rule 10b-5

403. Plaintiffs repeat and re-allege each and every allegation above as if set forth fully herein.

404. During the Relevant Period, the Company was caused to make materially false and/or misleading statements, as well as omissions of disclosure of material adverse facts about, the Company's business, operations, and prospects. Specifically, the Company failed to disclose to investors that: (i) Vanda was engaged in a fraudulent scheme in which the Company promoted the off-label use of Fanapt and Hetlioz; (ii) Vanda defrauded the government by abusing Medicare, Medicaid, and Tricare programs; (iii) as a result of the scheme, Vanda faced a Qui Tam Lawsuit from the government; (iv) Vanda's promotional materials for Fanapt and Hetlioz were false and misleading, garnering regulatory scrutiny from the FDA; and (v) as a result, Defendants' statements about Vanda's business, operations and prospects were materially false and misleading and/or lacked a reasonable basis at all relevant times.

405. Thus, the price of the Company's shares was artificially inflated due to the deception of Defendants.

406. As such, the Defendants caused the Company to violate section 10(b) of the Exchange Act and SEC Rule 10b-5 in that they: (i) employed devices, schemes, and artifices to defraud; and (ii) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

407. As a result of the Defendants' misconduct, the Company was damaged as alleged herein.

408. Plaintiffs, on behalf of Vanda, have no adequate remedy at law.

Count V: Violations of Section 14(a) of the Exchange Act and Rule 14a-9

409. Plaintiffs repeat and reallege each and every allegation above as if fully set forth herein.

410. SEC Rule 14a-9, promulgated pursuant to section 14(a) of the Exchange Act, provides that no proxy statement shall contain "any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading." 17 C.F.R. §240.14a-9. The Company's Proxy violated section 14(a) of the Exchange Act and SEC Rule 14a-9 because it included materially false and misleading information and failed to disclose that the Company has been engaging in improper, misleading and fraudulent sales practices, which include: (i) promoting Fanapt and Hetlioz for off-label uses; (ii) overstating Fanapt's efficacy to providers; (iii) making false and misleading statements regarding Fanapt's safety warnings; (iv) misleading providers about Fanapt's approved dosing schedule; (v) improperly providing titration packets which did not have adequate instructions for use; (vi) promoting Fanapt as a first line therapy; (vii) fraudulently receiving drug

reimbursements from the government by abusing Medicare, Medicaid, and Tricare programs, as a result of which Vanda faced a Qui Tam Lawsuit from the government; (viii) Vanda's promotional materials for Fanapt and Hetlioz were false and misleading, garnering regulatory scrutiny from the FDA; and (ix) as a result, Defendants' statements about Vanda's business, operations and prospects were materially false and misleading and/or lacked a reasonable basis at all relevant times.

411. In the exercise of reasonable care, the Defendants should have known that the statements contained in the Proxy were materially false and misleading.

412. The misrepresentations and omissions in the Proxy were material to Company stockholders in voting on the matters set forth for stockholder ratification in the Proxy. The Proxy was an essential link in the accomplishment of the continuation of these Defendants' continued violation of their fiduciary duties.

413. The Company was damaged as a result of these Defendants' material misrepresentations and omissions in the Proxy.

414. Plaintiffs, on behalf of Vanda, have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

A. A judgment against all Defendants for the amount of damages sustained by the Company as a result of Defendants' wrongdoing as alleged herein;

B. Directing Vanda to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and protect Vanda and its shareholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for shareholder vote resolutions for amendments to the Company's By-Laws

and/or Articles of Incorporation, and taking such other action as may be necessary to place before shareholders for a vote the following corporate governance proposals or policies:

a. a proposal to strengthen Vanda's oversight of its disclosure procedures;

b. a proposal to strengthen the Company's controls over financial reporting;

c. a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater stockholder input into the policies and guidelines of the Board; and

d. a proposal to permit the shareholders of Vanda to nominate at least two candidates for election to the Board.

C. Awarding to Vanda restitution from Defendants, and each of them, including ordering disgorgement of all profits, benefits and other compensation obtained by Defendants;

D. Awarding Plaintiffs the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and

E. Granting such other and further relief as this Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiffs demand a trial by jury.

Dated: April 24, 2020

LEVI & KORSINSKY, LLP

/s/ Gregory Mark Nespole
Gregory Mark Nespole
Daniel Tepper
LEVI & KORSINSKY, LLP
55 Broadway, 10th Floor
New York, New York 10006
Tel: (212) 363-7500
gnespole@zlk.com
dtepper@zlk.com

Co-Lead Counsel to Plaintiffs

BRAGAR EAGEL & SQUIRE, P.C.

/s/ W. Scott Holleman
W. Scott Holleman
Lawrence P. Eagel
Garam Choe
885 3rd Avenue, Suite 3040
New York, New York 10022
Tel: (212) 355-4648
holleman@bespc.com
eagel@bespc.com
choe@bespc.com

LEVI&KORSINSKY LLP

55 Broadway, 10th Floor
New York, NY 10006
T:212-363-7500
F:212-363-7171
www.zlk.com

VERIFICATION

I, Samuel Williams, under penalties of perjury, hereby do declare that I am a plaintiff in the foregoing complaint, that I have read the complaint, and that the facts therein are true to my own knowledge, except to matters stated therein to be alleged upon information and belief, and as to those matters, I believe them to be true and correct to the best of my knowledge, information, and belief.

Signed: 

Print Name: Samuel Williams Date: 4/21/2020

IP: 99.203.75.175

VERIFICATION

I, Michael Bavaro, hereby verify that I have authorized the filing of the attached Consolidated Verified Stockholder Derivative Complaint, that I have reviewed the Consolidated Verified Stockholder Derivative Complaint and that the facts therein are true and correct to the best of my knowledge, information and belief. I declare under penalty of perjury that the foregoing is true

and correct.

April 21, 2020

Michael Bavaro

Michael Bavaro (Apr 21, 2020)

Michael Bavaro